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⑤④ **Laser system for providing target specific energy deposition and damage.**

⑤⑦ A hand piece (20) for use with a laser (14) includes a scanning mechanism which controls dosimetry of radiation applied to a target area (12) which is adjustable to limit thermal diffusion from the light absorbing portion of the irradiated target site for selective target specific energy deposition. When used for dermatologic purposes, the adjustable scanning mechanism permits radiation to impinge on tissue for a predetermined period of time for the selective necrosis of highly-filled blood vessels, while leaving adjacent tissue and empty blood vessels undamaged. The dwell time of the laser beam is designed to match the diffusion time for thermal destruction of the wall of the abnormal vessel, with the dwell time adjusted by the scanning rate.

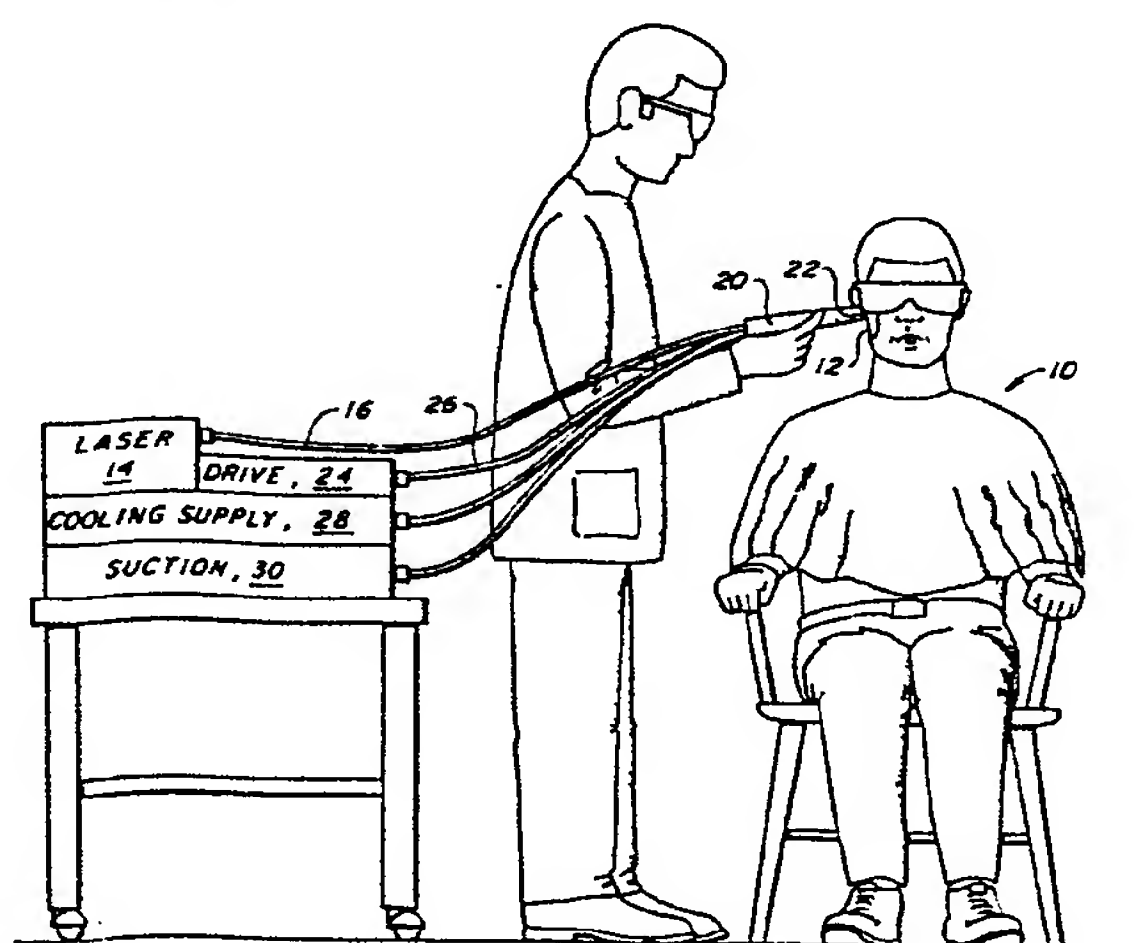


FIG. 1

FIELD OF INVENTION

This invention relates to medical treatment and, more particularly, to the control of a laser output in such a way as to limit the dwell time on any particular portion of the tissue, thus permitting target specific energy deposition and damage which is selective and controllable.

BACKGROUND OF THE INVENTION

There are many medical conditions, the treatment of which is substantially improved by being able to control the deposition of laser energy in a specific target tissue in order to damage that target tissue while sparing the adjacent tissue. While those in the past have utilized lasers, particularly in the port wine stain (PWS) syndrome, to destroy blood vessels, the problem associated with such systems is that the dwell time of the laser over the target produces significant thermal diffusion which damages not only the abnormal PWS vessels which are ectatic, i.e., dilated and filled, and strongly absorb the radiation, the ones producing the wine stain, but also damages a significant depth of the dermis such that scabbing and sloughing occurs as a consequence of treatment. Additionally, the use of an anesthetic is prescribed because of the amount of energy imparted to the target area which is painful to the patient. It will be appreciated that the desired treatment for port wine stains is to necrose only those vessels producing the stain while leaving most of the surrounding collagen and the normal vessels undamaged. This translates into control of thermal diffusion, which up until the present time has been difficult either because of the relatively long pulse lengths of the shuttered CW lasers utilized or because of the relatively short pulse lengths of the dye lasers which do not completely destroy the abnormal vessels.

1 Consequently, no successful control has heretofore been exercised to limit the
volume affected by thermal diffusion. The result of the lack of control is that
lasers which dwell on a given target area for 20 milliseconds or more produce so
5 much thermal diffusion that scabbing and sloughing of the epidermis and portions
of dermis are produced regardless of wavelength, assuming any kind of therapeutic
levels are introduced to the target area.

10 By way of further background, if it is desirable to destroy abnormal tissue
contained within the volume of normal tissue and spare the overlying normal layer,
differential absorption of the light is required. This can be obtained by either
intrinsic optical qualities of the target or tagging with some exogenous chromo-
15 phore. In the latter case, the wavelength or color of the laser must be selected on
the basis of the absorption spectra of both the target and the surrounding tissue. In
other words, it should be a wavelength where the target tissue is a good absorber
and the surrounding tissue is a poor absorber. Moreover, the irradiation time must
20 be selected on the basis of the thermal properties of the target and surrounding
tissue and the geometric shape and dimensions of the tissue structure.

Thus, in some cases the target tissue is distinguished from surrounding tissue
by a difference in absorption spectra either due to a naturally-occurring chromo-
25 phore (absorbing molecule) or due to the selective deposition of some dye used in
the treatment regimen. One important example of such a target tissue present
throughout the body is the vasculature which contains erythrocytes. The erythro-
cytes contain hemoglobin, a naturally-occurring chromophore with a broad usable
30 absorption band in the visible. The entire range of visible wavelengths shorter than
approximately 600 nm (nanometers) and extending into the ultraviolet is available
to purposely inflict damage to target tissues containing this chromophore. The
35 specific wavelength selected depends on the relative effects of scattering, which
varies with wavelength; the presence of other chromophores, such as melanin, in
the adjacent or overlying tissues; and the availability of light sources.

In selecting the exposure time, one is limited by the time which will confine thermal damage due to heat transport to an acceptable distance from the target. For the treatment of port wine stains, it is desirable to be in the regime where the dominant mechanism for heat transport is conduction. A characteristic thermal diffusion length for heat conduction is given by

$$L^2 = 4Kt$$

where L = distance that heat diffuses; K = thermal diffusivity coefficient; and t = time allowed for diffusion.

This formula varies slightly with the geometry of the irradiated target in surrounding media, but the variations are not significant. A typical thermal diffusivity coefficient for biological tissues is $0.0015 \text{ cm}^2/\text{second}$.

Considering, for example, the treatment of port wine stains, a type of hemangioma that consists of hypertrophic capillaries in the dermis causing a pink, red or purple coloring of the skin, the pink and red lesions are high in erythrocytes carrying oxygenated hemoglobin (HbO_2), while the purple lesions contain large quantities of deoxygenated hemoglobin (Hb). The lesions are characterized as consisting of abnormal capillary structure with the capillaries varying in diameter, the mean diameter being about 50 micrometers. The wall of the vessel, however, is only a few micrometers thick. The average vessel spacing is 100 micrometers. In order to damage the vessel containing the target hemoglobin, its wall, and a small portion of collagen surrounding the wall, the latter two being relatively free of chromophore, it is important to select an exposure time corresponding to thermal diffusion over a characteristic length slightly greater than the wall thickness. This, in general, refers to the delivery of radiation to a given target area of less than one millisecond. Those prior art devices which deliver 20 milliseconds or more cause damage due to thermal diffusion of heat to a distance

1 even greater than the vessel spacing. Thus the entire tissue bulk is heated by the
vessel network embedded within it and the damage is not at all selective.

5 J. L. Finley, S. H. Barsky and D. E. Geer in an article entitled "Healing of
Port Wine Stains After Argon Laser Therapy," Archives of Dermatology, 1981,
Volume 117, pps. 486-489, and J. L. Ratz, P. L. Bailin, and H. L. Levine in an
article entitled "CO₂ Laser Treatment of Port-Wine Stains: A Preliminary
10 Report," J. Dermatol. Surg. Oncol. 1982, vol. 8, no. 12, pps 1039-1044, describe
both argon lasers and carbon dioxide lasers used in the clinical treatment of port
wine stains. Neither of these provide an optimal treatment modality as the dwell
time is not limited to prevent thermal diffusion.

15 It will be appreciated that the CO₂ laser radiation whose wavelength is
approximately 10 micrometers is very strongly absorbed in water and most proteins.
In port wine stains, both the abnormal vasculature and the surrounding dermal
tissues are approximately 90% water and consequently absorb the incident laser
20 radiation and are heated to the point of thermal necrosis. Thus this treatment does
not involve any specificity of damage. The necrotic tissue eventually sloughs off
and is replaced via the normal healing process by scar tissue formation. Since the
scar tissue formed is usually flat and white, it is often more acceptable to the
25 patient than the original dark and, sometimes, hypertrophic lesion.

Present treatment of port wine stains with the argon laser is performed
using comparatively long pulse times. Because of this, heat has time to diffuse to
30 the surrounding tissue, and the effect observed is the same as for the CO₂ laser in
which radiation is uniformly absorbed in both vascular and surrounding tissue. The
similarity of clinical results with the CO₂ and the long pulse argon lasers has been
noticed and documented in an article by J. W. Buecker, J. L. Ratz and D. F.
35 Richfield entitled "Histology of Port Wine Stains Treated with CO₂ Laser," Fifth
International Conference of Laser Medicine and Surgery, Detroit 1983, in an

abstract. Thus the nonspecificity of prior art laser treatment of port wine stains is both documented and explainable by the relatively long irradiation times causing massive long-distance thermal diffusion for argon lasers and the non-specific absorption for CO₂ lasers.

By contrast ultrashort laser pulses have been used. Studies by R. R. Anderson and J. A. Parish entitled "Microvasculature Can Be Selectively Damaged Using Dye Lasers: A Basic Theory in Experimental Evidence in Human Skin," Lasers in Surgery and Medicine, 1981, Volume 1, pps. 263-276, show that when utilizing pulse dye lasers with fluence level on the order of 3 to 5 Joules/cm² and exposure times of approximately 300 nanoseconds (ns) target specific damage may be produced in normal blood vessels. The wavelength used was 577 nanometers. While the above pulse width was short enough to restrict thermal diffusion to a small portion of the individual erythrocytes having typical dimensions of 7-15 micrometers carrying the hemoglobin, and thermal diffusion subsequent to the pulse could have allowed heating of the containing vessel without damage to the surrounding tissues, the short 300-nanosecond duration caused the vessels to burst and to spew forth blood. It is possible that a shock wave produced by the ultrashort pulse ruptured the blood vessels causing formation of purpura. Since the vessels are 50 μ in diameter and the wall is about 1 μ thick, the pulse is so short that only the hemoglobin itself (which is the optical absorber) and any spot on the inner edge of the wall which happens to be in intimate thermal contact with the hemoglobin bearing portion of an erythrocyte are heated during the pulse. After the pulse, the peak temperature achieved within the vessel decays as heat diffuses away. While regions outside the vessel are in fact heated as this diffusion occurs, it is not possible to achieve thermal damage to an adequate depth to insure permanent vessel necrosis.

1 Note that at the present time several microseconds is the longest pulse time
available from commercial pulsed dye lasers. This is still too short to achieve the
desired effect.

5 In summary, it will be appreciated that the difficulty in the prior art
methods of utilizing argon laser treatment lies not in the wavelength, at least for
low melanin skins, but in the exposure time utilized. The argon lasers are CW
lasers which are mechanically shuttered to provide pulsewidths which may vary
10 from 20 milliseconds to 100 milliseconds or more. Even the shortest of these
exposure times, 20 milliseconds, results in thermal diffusion to a length of 100
micrometers which is equal to the average spacing between targets. Thus, even if
the laser power is initially absorbed only in the target volumes, thermal diffusion
15 during the laser pulse itself provides nearly uniform heating of the entire irradiated
area. In order to achieve true specificity, damaging only the target vessels, the
exposure time must be limited to about one millisecond or less, which is too short
20 to be achieved with the mechanical shutters presently in use. Additionally,
nanosecond pulses from dye lasers cause blood vessel rupture and causes only
partial necrosis. Thus these techniques are not optimally useful in treating port
wine stains.

25 Note the following U.S. patents deal with scanning lasers: 3,362,007;
3,642,007; 4,069,823; and 4,316,467; whereas U.S. patents dealing with coaxial bi-
laser beams include 3,456,651; 3,710,798; 3,769,963; 3,906,953; 3,910,276; 4,240,431
and 4,408,602. Finally, U.S. patent 3,434,476 deals with a plasma arc scalpel.
30

SUMMARY OF THE INVENTION

35 In order to limit thermal diffusion, apparatus is provided which moves the
focused laser beam in a circle or other path which controls dosimetry of radiation

1 applied to a target area, with the scanning rate being adjusted to limit thermal
diffusion from the irradiated target site for selective target specific energy
deposition. In one embodiment, a hand piece is used in which the scanning is
5 provided by rotating optics within the hand piece, with the speed of rotation
determining the scanning rate. In an alternative embodiment the scanning may be
provided by a rigidly mounted head containing the scanning optics. When used for
dermatologic purposes, the adjustable scanning mechanism prevents radiation from
10 impinging on tissue for more than about one millisecond in one embodiment for the
selective necrosis of highly-filled port wine stain blood vessels, while leaving
adjacent tissue undamaged. The dwell time of the laser beam is designed to match
the thermal diffusion time for destruction of the wall of the abnormal vessels, and
15 some surrounding collagen with the dwell time adjusted by the scanning rate.
Neither the small, empty normal vessels nor the collagen adjacent the normal
vessels are attacked by the impinging radiation since they contain no absorbing
chromophore. In one embodiment, a CW laser is used, with the time per scan
20 being maintained at less than 60 milliseconds to give the visual impression of a
continuous ring of light to the operator, with a rotary scan diameter of 2.8
millimeters and a focal spot size of 0.14 millimeters. The wavelength of the laser
25 is held below 600 micrometers so that the hemoglobin in the erythrocytes absorb
sufficient radiation for the necrosis of the vessels containing the erythrocytes.
While the subject invention will be described in connection with CW lasers, pulsed
lasers may be used and are within the scope of this invention.
30

In one embodiment the simple hand piece for a CW laser is provided with
cooling apparatus involving a cooling ejectant line and a cooling suction line on
opposite sides of the nose of the hand-held device. In a further embodiment,
35 bleachable indicators are painted onto the skin prior to usage to indicate to the
operator what areas of the epidermis have been irradiated.

1 It has also been found that to reduce the chances for regeneration of a
 lesion it is possible to slightly lengthen the pulse which is delivered to the given
 target area extending the thermal damage into the collagen immediately sur-
 5 rounding the abnormal vessel. An exposure time of about one millisecond allows
 heating as far as 20 micrometers from the edge of the abnormal vessel. This is
 adequate to insure total vessel destruction but is still small compared with the
 spacing between vessels, insuring sparing of a significant volume of the dermis.
 10 The exact exposure time involves the correlation between the length of thermal
 diffusion damage and redevelopment or final destruction of the lesion. Other
 considerations include the fluence level of the focused light required to produce
 the desired damage effect and the depth of field, it being understood that the
 15 target tissue must be raised to an adequate temperature for a sufficient length of
 time to produce thermal necrosis.

In order to achieve adequate fluence levels from available laser systems, the
 20 laser beam diameter and depth of field are controlled by any of a variety of
 focusing techniques. The depth of field is made large enough to compensate for
 any variation in the distance between the target and the delivery system whether
 this distance is maintained by a mechanical fixture or simply by the operator's
 25 hand. Note that a larger depth of field makes the control of the distance between
 the delivery system and the skin less difficult. The larger depth of field is also
 useful because, when the skin is depressed by as little as one millimeter by the nose
 of the tool, this can cause a 1 millimeter bulge inside the nose of the instrument.
 30

Other uses for the subject invention include the treatment of other
 cutaneous vascular lesions such as telangiectasias, nevus araneus, strawberry
 nevus, cavernous hemangiomas, cherry hemangiomas, and venous lakes. The
 35 treatment of deep, cavernous hemangiomas is expected to require multiple
 treatments since these lesions are so hypertrophic that vessels nearest to the

1 surface will optically shield underlying vessels. By causing thermal necrosis of the
surface vessels and permitting adequate time for phagocytic removal of the
necrotic tissue, the next layer of vessels is made vulnerable to the laser
5 irradiation. It should be noted that laser wavelength may also be a more important
consideration in treating very deep lesions since very strongly absorbed wave-
lengths will provide shallower depth of necrosis per treatment. Another use for the
invention is in the treatment of psoriasis. Psoriasis is characterized by an
abnormal, ectatic and hypertrophic vasculature, along with other abnormal
features. Selective destruction of the vascular component permits destruction of
the lesion without subsequent tissue inflammation and psoriatic regeneration.

The device is also useful in the treatment of various forms of neovascular-
ization of the eye including diabetic retinopathy and senile macular degeneracy.
For this type of lesion a microscopic rather than hand held delivery system is
required. In the case of retinal disorders, where melanin absorption in the retinal
pigment epithelium could cause undesirable remote heating, a line scan, operator
defined and computer controlled, allowing the scan to exactly follow the vascular
line would be preferable. However, even full area scanning would destroy less
tissue than present modalities for treating each of these diseases. The currently
accepted modality calls for intentional destruction of large tissue volumes to
reduce the production of angiogenic substances. The scanner described herein,
however, has the potential to limit damage to such small volumes that frequently
repeated treatments, with greater preservation of visual acuity may be possible.

Another use for the device is in the treatment of structures bearing
melanosomes, including actinic keratoses, lentigo, malignant melanomas, and
freckles. In this case the dwell time (i.e., scanning rate) is adjusted to destroy the
melanosome bearing cells, leaving adjacent cells unharmed.

1 BRIEF DESCRIPTION OF THE DRAWINGS

5 These and other features of the subject invention will be better understood
in connection with the detailed description taken in conjunction of which:

 Figure 1 is diagrammatic representation of the utilization of the scanning
hand piece in the treatment of a typical port wine stain;

10 Figure 2 is a diagrammatic illustration of the operation of the hand piece of
Figure 1 illustrating a focal spot which moves around in a circular scan within the
nose of the hand piece while the hand piece is moved across the area to be
irradiated, liquid cooling and suction pipes being utilized to provide fluid which
15 cools the irradiated area;

 Figure 3A is a cross-sectional and diagrammatic illustration of one embodi-
ment of the hand piece in which a rotating offset lens is utilized to scan the
focused beam in a circular pattern;

20 Figure 3B is a diagrammatic and cross-sectional illustration of an alterna-
tive device utilized for the scanning of the beam by providing a rotating optical
wedge interposed in the optical path;

25 Figure 4 is a top view and schematic diagram of the circular scan produced
by the hand pieces of Figure 3A and Figure 3B;

30 Figure 5 is a diagrammatic representation of the result of irradiation of a
port wine stain with the prior art ultrashort laser pulses, illustrating the rupturing
of the port wine stain blood vessels causing the spewing forth of blood;

 Figure 6 is a diagrammatic representation of the result of irradiation of a
port wine stain with a prior art CW or long pulse laser showing complete necrosis
of all irradiated areas, and;

35 Figure 7 is a diagrammatic representation of the result of utilizing the
subject scanning system in which thermal diffusion is limited, causing necrosis of

1 the port wine stain blood vessel, its wall and a very small portion of the collagen
immediately adjacent the vessel wall, without disruption of the majority of the
normal tissue within the port wine stain area.

5

DETAILED DESCRIPTION

0 Referring now to Figure 1, in one embodiment a patient 10 having a port
wine stain 12 is being treated by laser radiation from a laser source 14 which is
channeled by fiber optic cable 16 to a hand-held unit 20 which has therein internal
optics utilized to provide scanning of a beam within the nose portion 22 of the tool.
5 This is accomplished in one embodiment through drive motor 24 utilized to control
the scan speed by rotating cable 26 which drives a hollow cylindrical barrel in the
tool that carries the focusing optics. Alternatively, air drive motors or small
electrical motors may be used in the hand piece to drive the rotating optics.
10 Hollow shaft motors (either electrically or pneumatically driven) may incorporate
the optical path within the hollow shaft, supporting the rotating element on the end
of the shaft. Solid shaft motors must be used with gear or other coupling
mechanisms to drive the rotating element. An optional source of cooling liquid 28
5 is applied to the hand tool which is channeled to the nose portion 22 and is removed
by a suction unit 30 such that the area of the target adjacent the nose of the tool is
cooled.

10 The operation of the hand tool can be better seen in conjunction with
Figure 2 in which like reference characters are utilized between Figures 1 and 2.
In Figure 2 an optical system 32 is utilized to focus and rotate a focal spot 34 such
that in the illustrated embodiment the spot rotates in a circle 36 as illustrated by
5 the dotted arrow. Cooling fluid is delivered at one side of nose 22 by a delivery
tube 38 and is removed by a suction tube 40 as illustrated.

1 It is the purpose of the rotating optics within the hand tool to scan the focal
spot such that it resides over a target for no longer than about one millisecond in
one embodiment. The control of the scan rate controls the time that the focused
5 spot resides at a given location within the target area and is readily adjustable by
the scan rate. While a circular scan is illustrated in the embodiment of Figure 2, it
will be appreciated that raster scan, Rosette type, orbital, elliptical, or other scan
patterns scans may be performed by optics to prevent the focal spot from residing
10 at any given location for longer than a predetermined period of time. In one
embodiment the depth of field is made greater than two millimeters by virtue of
the focal system aperture utilized. In this embodiment, a focal spot size of 0.14
15 millimeters, a scan pattern diameter of 2.8 millimeters, and a scan rate of less
than 60 milliseconds per cycle are used. For port wine stains, the wavelength of
the laser is held below 600 micrometers so that the hemoglobin in the erythrocytes
absorbs sufficient radiation to provide for the necrosis of the vessels containing the
20 chromophores.

 In one operative mode, the hand piece is moved in a serpentine fashion as
illustrated by dotted arrow 33 across an area 46 which corresponds to the area of
the port wine stain.

25 As mentioned before, a dye may be first applied to the affected area which
changes color upon irradiation by focal spot 34 such that the treated area may be
ascertained with a high degree of certainty. This aids the operator who may be
30 unable "see" which areas have been treated since the treatment is so gentle as to
provide minimal visible color change of the lesion. The actual lightening of the
lesion occurs slowly, over a period of days to weeks as the body phagocytizes the
necrotic tissue. Instead of a hand held unit, the same treatment may be provided
35 by a programmed scanner. In such a case the indicating dye would not be
necessary.

Referring to Figure 3A, hand tool 20 may take on a configuration in which a body 50 includes a hollow cylindrical barrel illustrated at 52 to be rotated via cable 26 or other means about an axis 54 which is typically the central axis of the hand tool. The barrel is supported via a bearing system generally indicated by bearings 56.

Laser radiation is transmitted to the hand tool via fiber optic cable 16 which is coupled via a cable termination 60 to a lens 62 which collimates the light generally along axis 54. A lens 64 having a convex surface 66 focuses the parallel light as indicated by dotted lines 70 to a point 72 on the surface of skin 74. Since the optical axis of the lens is offset from centerline 54, its rotation via a barrel 52 causes the focal spot 72 to rotate on the surface of the skin 74. As can be seen, cooling liquid may be introduced through tube 38 such that liquid proceeds across the irradiated areas illustrated by 76 to suction tube 40.

The same system may include as a scanning means an optical wedge 80 which is shown in Figure 3B in which like apparatus is given like reference characters vis-a-vis Figure 3A. Note that power to rotate each of the barrels of Figures 3A and 3B is delivered by line 26, be it mechanical, electrical, hydraulic, or pneumatic. Note also that a fixed lens 82 is provided in nose 22 of the hand tool to achieve focusing.

Indeed, any focusing optics which is moved so as to provide a scanning beam, be it a raster scan, a circular scan, a line scan, or an elliptical scan, or some combination of these is within the scope of this invention. It is only important that the focal spot 72 not remain over any point within a target area 74 for any longer than is necessary for the particular purpose intended. For port wine stains this means that the dwell time for the spot should be on the order of one millisecond in order to prevent the type of damage which will now be described.

1 Prior to describing the damage done by thermal diffusion for radiation
impinging upon the skin for too long a period of time and referring now to Figure 5,
when using ultrashort pulses to treat port wine stains, it will be appreciated that
5 the abnormal, ectatic vessels are those illustrated by reference character 92. Each
of these vessels is nearly completely filled with blood and has a wall 94 thickness
of approximately 1-2 microns. Normal blood cells are indicated by reference
character 96 and are shown to be approximately 1/10 the size of the inflated port
10 wine vessels, with the spacing between the vessels being approximately 100
microns and with the diameter of the port wine stain vessels being 50 microns,
whereas the average diameter of the normal vessels is approximately 5 microns.
15 This is, of course a highly schematic illustration, using "average" values. Actual
vessel sizes and spacings vary widely.

What happens with the ultra-short pulses is that the thermal diffusion as
illustrated by arrows 102 is not sufficiently long to necrose both the blood in the
20 port wine stain vessel as well as the vessel wall. Rather what happens is that the
vessel wall is ruptured due to the ultrashort pulse thereby bursting the vessel and
causing blood to spurt out as illustrated at 104. This is highly undesirable due
primarily to the fact that the blood spurting through the surrounding tissue here
25 illustrated by reference character 100, interferes with further irradiation. In
addition this point by point pulsed irradiation is very tedious for the operator.

Referring to Figure 6, CW or a long pulse radiation causes a necrosis not
30 only of the blood within the port wine stain vessels 92 but also necroses the
collagen between the vessels as well as normal vessels 96. For example, a 50 msec
pulse gives 170 micron thermal diffusion length from each absorbing vessel, such
that there is an overlap in the manner illustrated, with the result that the entire
35 irradiated area is damaged as shown by the shading.

1 Referring now to Figure 7, when the dwell time for the radiation is limited
to approximately one millisecond in the subject system, the area necrosed is
indicated to include the port wine stain vessel 92 and extends approximately 20
5 micrometers (microns) into the tissue immediately adjacent the port wine stain
vessels. It will be noted that little of surrounding tissue 100 and few of the normal
vessels 96 are affected. The subject technique thus leads to a relatively painless,
treatment for the port wine stain syndrome, without extensive tissue damage,
0 sloughing, and scab formation.

Damage induced by thermal diffusion as illustrated by wavy arrows 102 may
be controlled in length by virtue of the spot size and the scanning time, which is
5 controllable to the extent necessary to preclude damage to the majority of the
avascular tissue and the normal blood vessels within the port wine stain. As
mentioned before, for a focal spot size of 0.14 millimeters and a scan diameter of
2.8 millimeters with a cycle time 60 milliseconds, even without the utilization of
0 external cooling, the necrosed area is limited to 20 microns from the walls of the
vessels which are enlarged and are filled with blood, whereas the vessels that are
normal and generally less than 10 percent of which are filled with blood at any
point in time, are virtually unaffected. Note that the aforementioned cooling may
5 be added for patient comfort, to avoid the use of anesthetic, and to increase the
specificity of the treatment.

It will be appreciated that one difference between the subject treatment
and that of Figure 5 is that the abnormal vessel is necrosed without the spurting
0 forth of blood which decreases the effectiveness of treatment. The present
technique is more effective than completely necrosing the whole port wine stain
area because the sloughing associated with the prior art technique of Fig. 6 is
5 eliminated. Thus a painful and time-consuming procedure is replaced through the
utilization of the control of the dwell time of the radiation impinging on the target

1 area to an extent not heretofore possible, thereby effectuating a treatment that
may be used without anesthetic and which achieves the desired result without large
amounts of scabbing and sloughing.

5 It will be appreciated that the control of laser radiation through the
scanning device described in this invention is applicable to other situations which
require a controlled amount of energy be delivered to a given absorbing target site.
Thus for instance the subject technique is applicable to treatment of any abnormal,
0 ectatic vasculature, any highly filled vasculature within tissue, any preferentially
stained (for laser absorption) target tissue whether or not embedded in normal
tissue to be spared. With appropriate choice of laser wavelength it may be used to
5 destroy non-vascular pigmented targets, in particular melanin bearing tissues such
as actinic keratosis, lentigo, malignant melanoma, or portions of the retinal
pigment epithelium.

Having above indicated a preferred embodiment of the present invention, it
) will occur to those skilled in the art that modifications and alternatives can be
practiced within the spirit of the invention. It is accordingly intended to define the
scope of the invention only as indicated in the following claims:

CLAIMS

What is claimed is:

1. Apparatus for use with a laser comprising a scanning mechanism which controls the dosimetry of radiation applied to a target area, said scanning mechanism being adjusted in scanning rate to limit thermal diffusion from the light absorbing portion of the radiated target site for selective target specific energy deposition.

2. The apparatus of claim 1 wherein said apparatus includes a hand piece having an apertured nose and wherein said apparatus further includes:

means including said laser for generating laser radiation;

means including fiber optic means for coupling radiation from said laser to said hand piece; and

means within said hand piece for focusing the radiation from the output of said fiber optic means and for providing a scanning pattern of said focused radiation at the nose of said hand piece.

3. The apparatus of claim 2 and further including means carried by said hand piece for cooling the area adjacent the nose of said hand piece.

4. The apparatus of claim 2 wherein said scanning means includes means for inducing a rotary scan of the focused radiation from the output of said fiber optic means.

- 1 5. The apparatus of claim 4 wherein said rotary scan means includes a hollow
rotatable shaft having a centerline, said shaft being located within said hand piece,
and means for rotating said shaft, said focusing means being mounted to said
5 hollow cylindrical shaft such that said focusing means is offset from the centerline
of said hollow cylindrical shaft so as to provide for a rotary scan of the focused
radiation from said laser, the dwell time of the focal spot at the nose of said hand
piece being controlled by the speed of rotation of said hollow rotational shaft.
10
6. The apparatus of claim 5 wherein said offset focusing means includes a lens
offset from the centerline of said rotatable shaft.
- 15 7. The apparatus of claim 4 wherein said rotary scan means includes a hollow
rotatable shaft within said hand piece, and further including an optical wedge
mounted to said hollow rotatable shaft, said focusing means including a fixed lens
20 in the nose of said hand piece.
8. The apparatus of claim 1 wherein said scanning mechanism includes means
for focusing radiation from said laser to produce a focal spot and wherein said
25 scanning rate is adjusted such that the dwell time of said focal spot is no longer
than the time required to damage the tissue targeted for destruction.
- 30 9. The apparatus of claim 1 and further including means for adjusting the dwell
time of the radiation applied to said target area to be less than the time required
to damage the tissue targeted for destruction.
- 35 10. A method for the treatment of port wine stains comprising irradiating the
port wine stain with focused laser radiation which is scanned in a pattern which

1 limits the dwell time of the focused radiation on the area to a time sufficient to
selectively necrose highly filled blood vessels, while leaving adjacent tissue and
empty blood vessels undamaged.

5

11. The method of claim 10 wherein said scanning includes providing a rotary
scanned beam of laser energy which is focused to a focal spot and which is caused
to scan in a predetermined pattern across the port wine stain such that the focal
spot does not dwell on any target area for any more than 1 millisecond.

12. The method of claim 10 wherein said scanning is accomplished at a rate
which limits the thermal diffusion length of heat generated when said focused laser
radiation impinges on the port wine stain.

13. The method of claim 12 wherein said thermal diffusion length is limited to a
distance corresponding to the average wall thickness of a highly filled blood vessel
and a predetermined small amount of surrounding tissue.

14. The method of claim 13 wherein said predetermined amount of collagen
exists no more than 20 microns away from the outside wall of a highly filled blood
vessel.

15. The method of claim 10 wherein said radiation is generated by a CW laser.

16. The method of claim 10 wherein the dwell time of the focused laser
radiation is designed to match the thermal diffusion time for destruction of the
wall of abnormal vessels and a small portion of the surrounding collagen, with the
dwell time being adjusted by the scanning rate.

1 17. The method of claim 10 wherein a CW laser is used, wherein a rotary scan is
used with a time per scan being maintained less than 60 milliseconds, with the
rotary scan diameter of the focused radiation being 2.8 millimeters and wherein,
5 the focused radiation forms a spot having size of 0.14 millimeters, the wavelength
of the laser being below 600 micrometers.

10 18. A method for the selective destruction of a vascular component comprising
radiating a target area on the human body with a focused beam of laser radiation,
which beam of laser radiation is scanned across the area in such a manner that the
dwell time of the focused beam is controlled such that the focused radiation
15 produces a thermal diffusion which is limited by the scan rate, thereby providing
selective necrosis of predetermined components of the human body while leaving
other components of the human body undisturbed.

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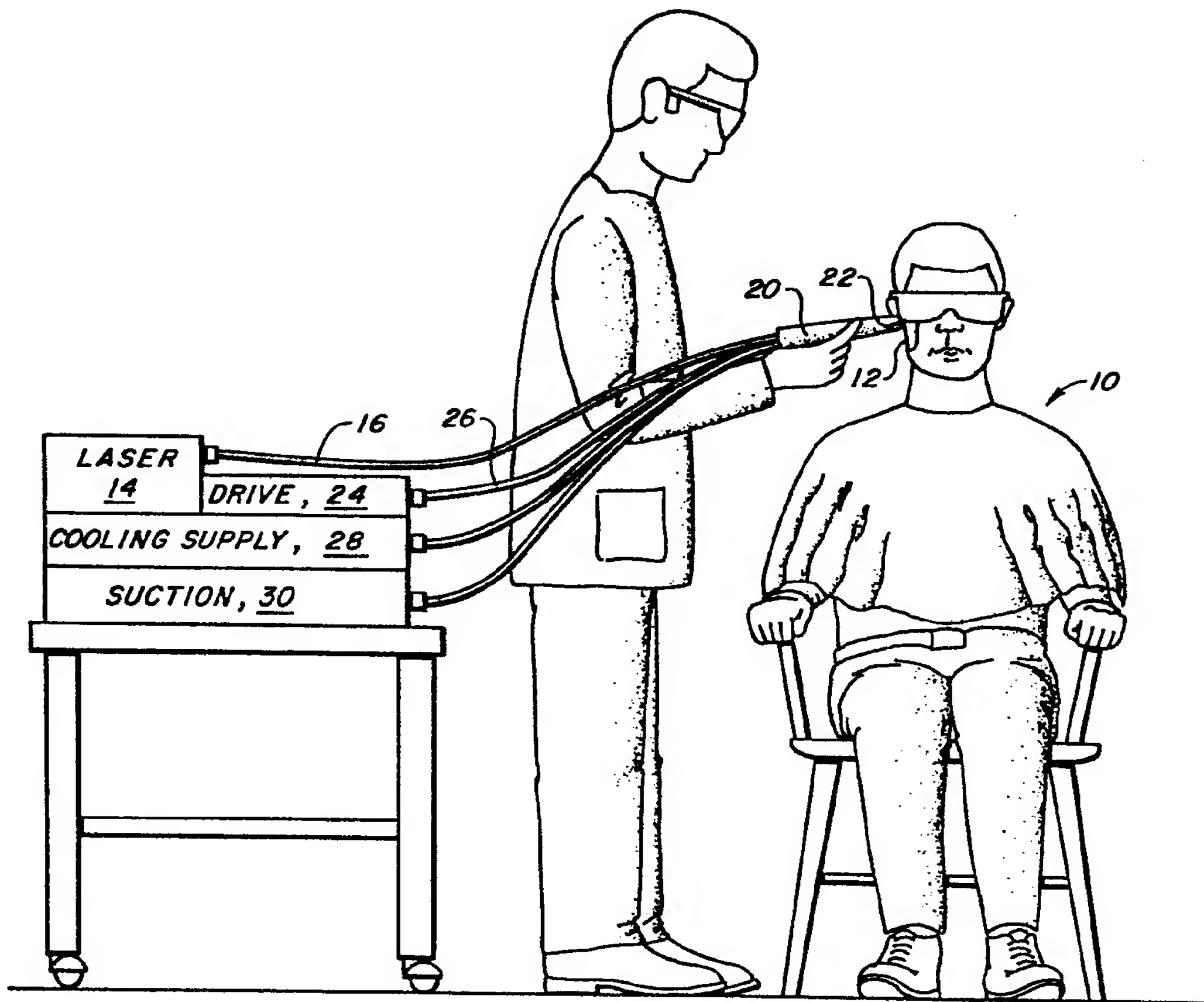


FIG. 1

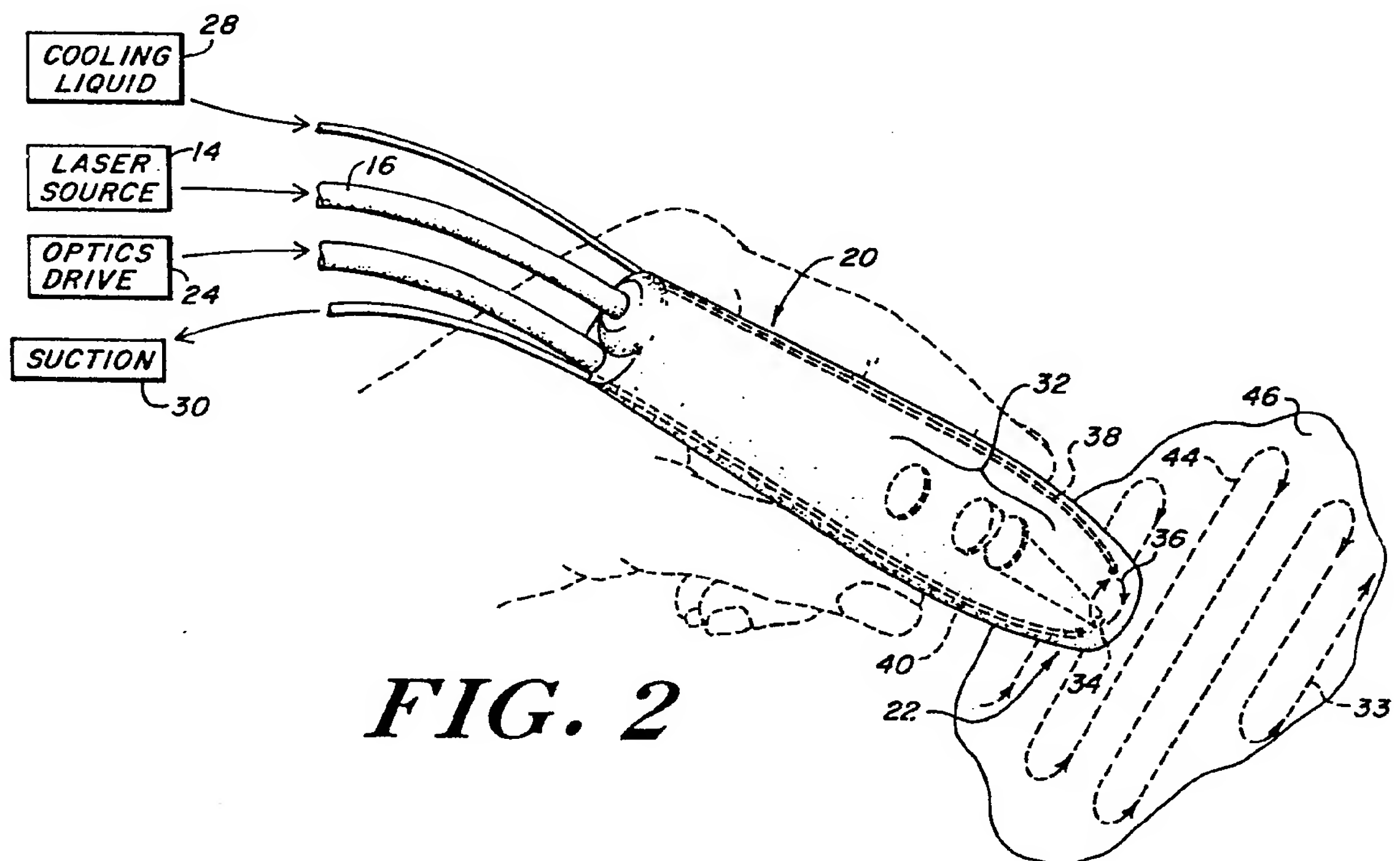


FIG. 2

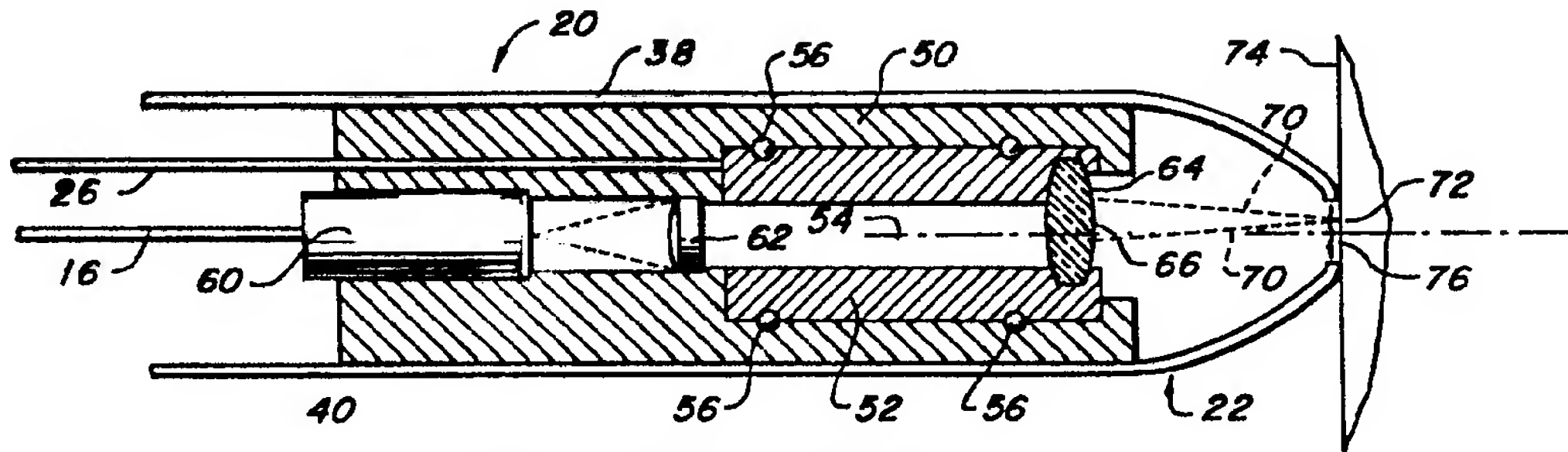


FIG. 3A

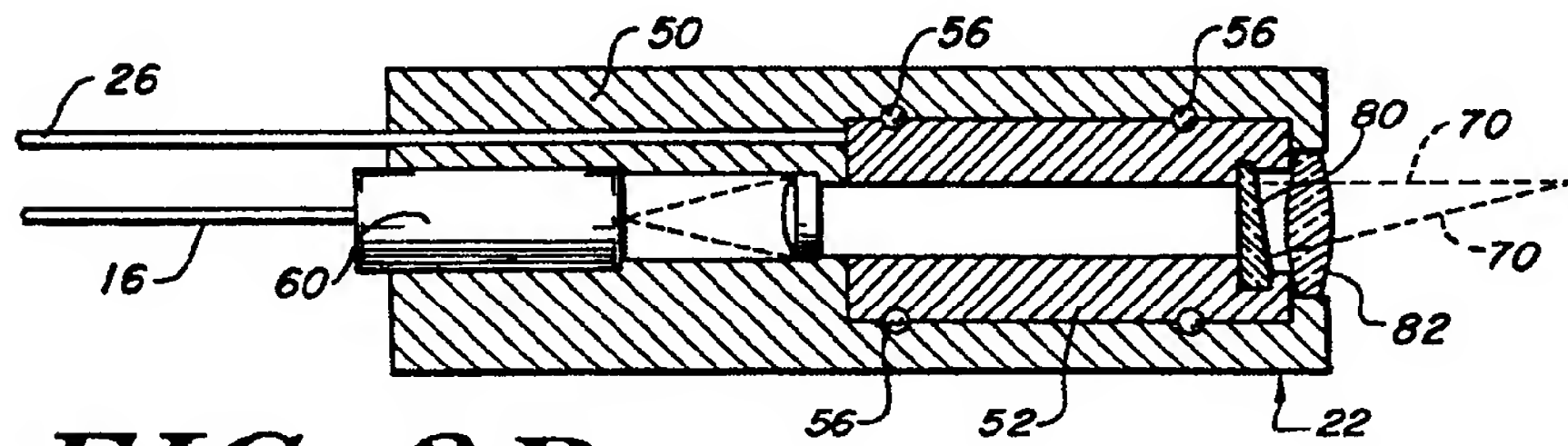


FIG. 3B

FIG. 4

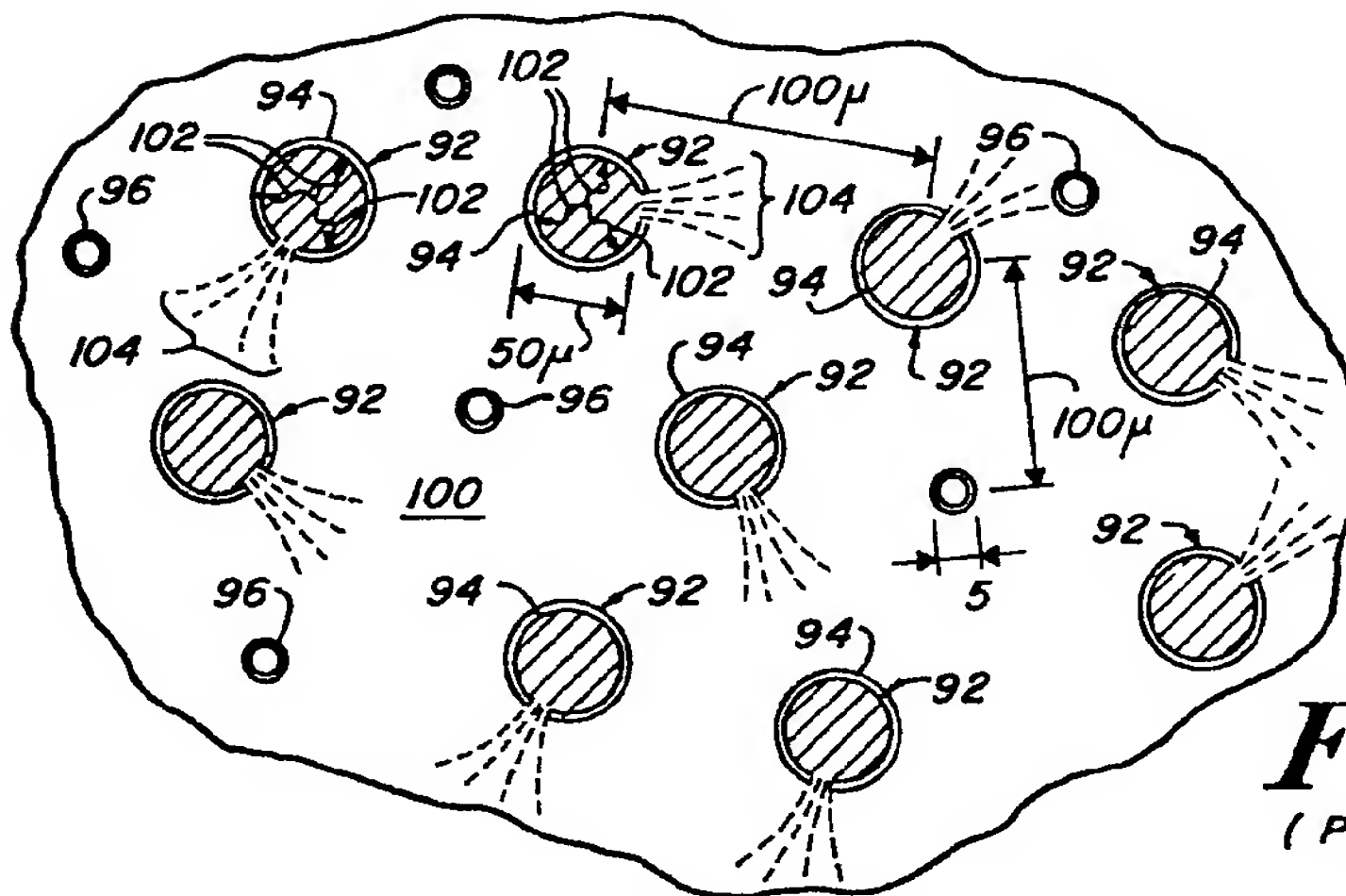
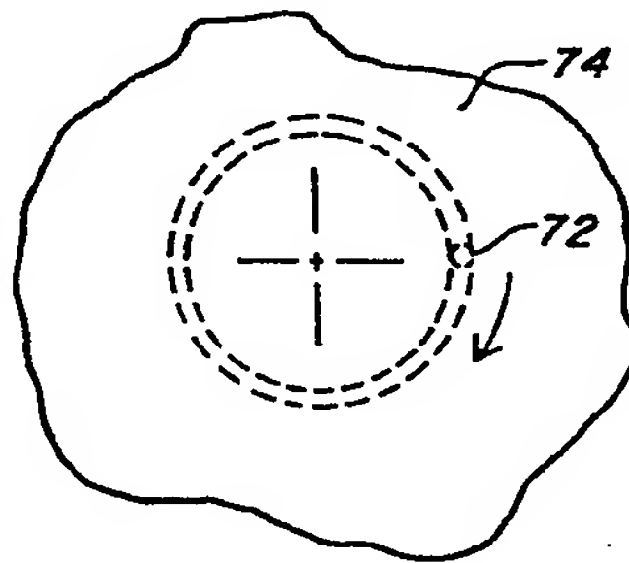


FIG. 5
(PRIOR ART)

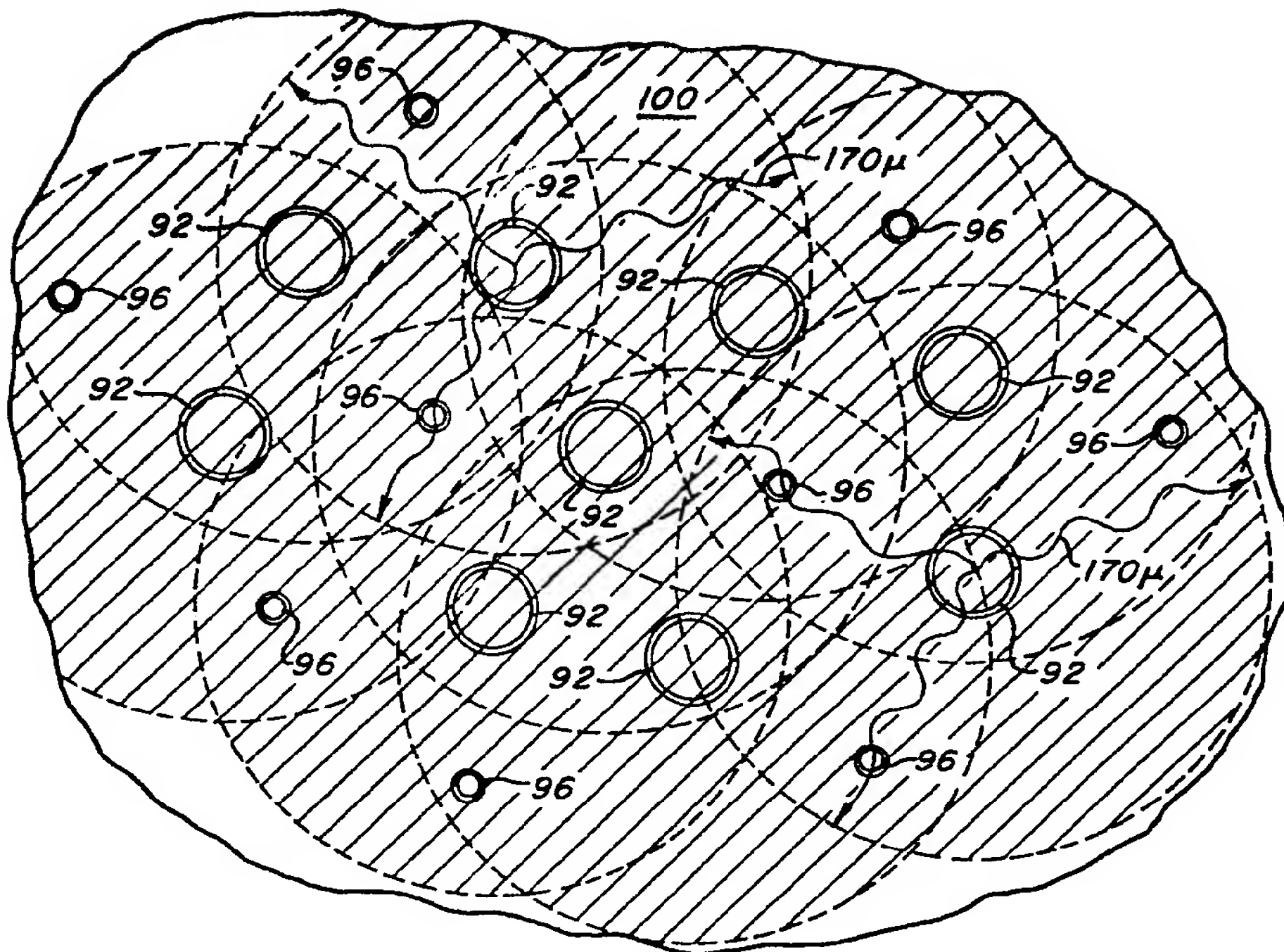


FIG. 6
(PRIOR ART)

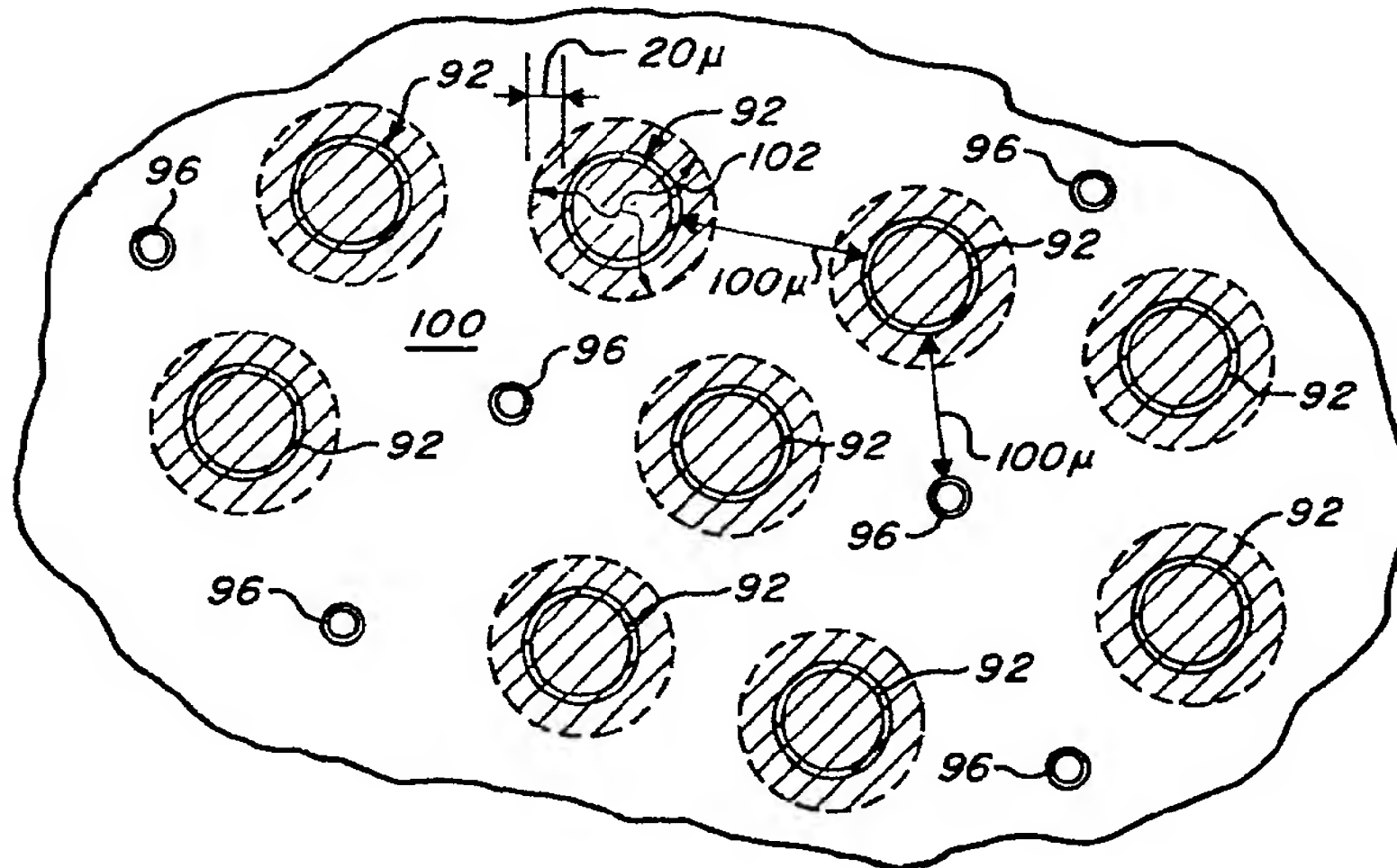


FIG. 7



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Office

PARTIAL EUROPEAN SEARCH REPORT
which under Rule 45 of the European Patent Convention
shall be considered, for the purposes of subsequent
proceedings, as the European search report

0172490

Application number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 85109894.7
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
X,D	US - A - 4 069 823 (ISAKOV) * Abstract; column 2, line 61 - column 3, line 30; column 3, line 59 - column 4, line 19; fig. 3,5 *	1,2	A 61 B 17/36 A 61 N 5/06
	--		
X,D	US - A - 4 316 467 (MUCKERHEIDE) * Abstract; column 1, line 65 - column 2, line 19; fig. 1 *	1,2	
	--		
X	EP - A2 - 0 075 912 (HITACHI) * Abstract; page 3, line 13 - page 4, line 5; fig. 2,6,13, 15 *	1,2	
	--		
P,A	EP - A2 - 0 130 950 (TESSIORE) * Abstract; page 2, last paragraph - page 3, first paragraph; page 4, line 22 - page 5, line 19 *	1,2,4	TECHNICAL FIELDS SEARCHED (Int. Cl. 4) A 61 B A 61 N
INCOMPLETE SEARCH --			
<p>The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims</p> <p>Claims searched completely: 1-9 Claims searched incompletely: -- Claims not searched: 10-18 Reason for the limitation of the search:</p> <p>according to Art. 52(4)</p>			
Place of search VIENNA		Date of completion of the search 27-11-1985	Examiner NEGWER
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	



DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
A	<u>EP - A1 - 0 074 914 (SERIEL)</u> * Page 9; claims 1,2 * --	1,2,4	
A	<u>US - A - 3 653 384 (SWOPE)</u> * Abstract; column 1, line 66 - column 2, line 8 * --	1,2,4, 5	
A	<u>US - A - 3 821 510 (MUNCHERYAN)</u> * Abstract; column 2, lines 48-66 * --	1-3	
X	<u>DE - A1 - 2 829 516 (MESSERSCHMITT)</u> * Page 5, line 8 - page 6, line 13; fig. 4,5,7 * --	1,2	TECHNICAL FIELDS SEARCHED (Int. Cl. 4)
X	<u>DE - A1 - 3 245 846 (MITSUBISHI)</u> * Abstract; page 1, claim 1; fig. 1,3,6 * ----	1,2	

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EUROPEAN PATENT APPLICATION

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54 **Device and system for biostimulation of tissue.**

57 A device for biostimulation of tissue is disclosed comprising an array of substantially monochromatic radiation sources of a plurality of wavelengths, preferably of at least three different wavelengths. The radiation sources are arranged within the array such that radiation of at least two different wavelengths passes directly or indirectly through a single point located within the treated tissue. The radiation sources are preferably laser diodes, superluminous diodes or similar light-emitting diodes that, while low-power radiation sources, can provide significant energy densities to a treatment area. A method of treatment of tissue comprising exposing the treated tissue to the above-described device is also disclosed. The device for biostimulation of tissue may be included within a system with a control panel (20), a power source (40), means (47) for varying pulse frequency, means for varying pulse duration, means (72) for timing the period of treatment, means (75) for measuring the conductivity of the treated tissue, means for measuring the optical power emitted by the radiation sources and/or means (30) for detecting emissions from the radiation sources.

EP 0 320 080 A1

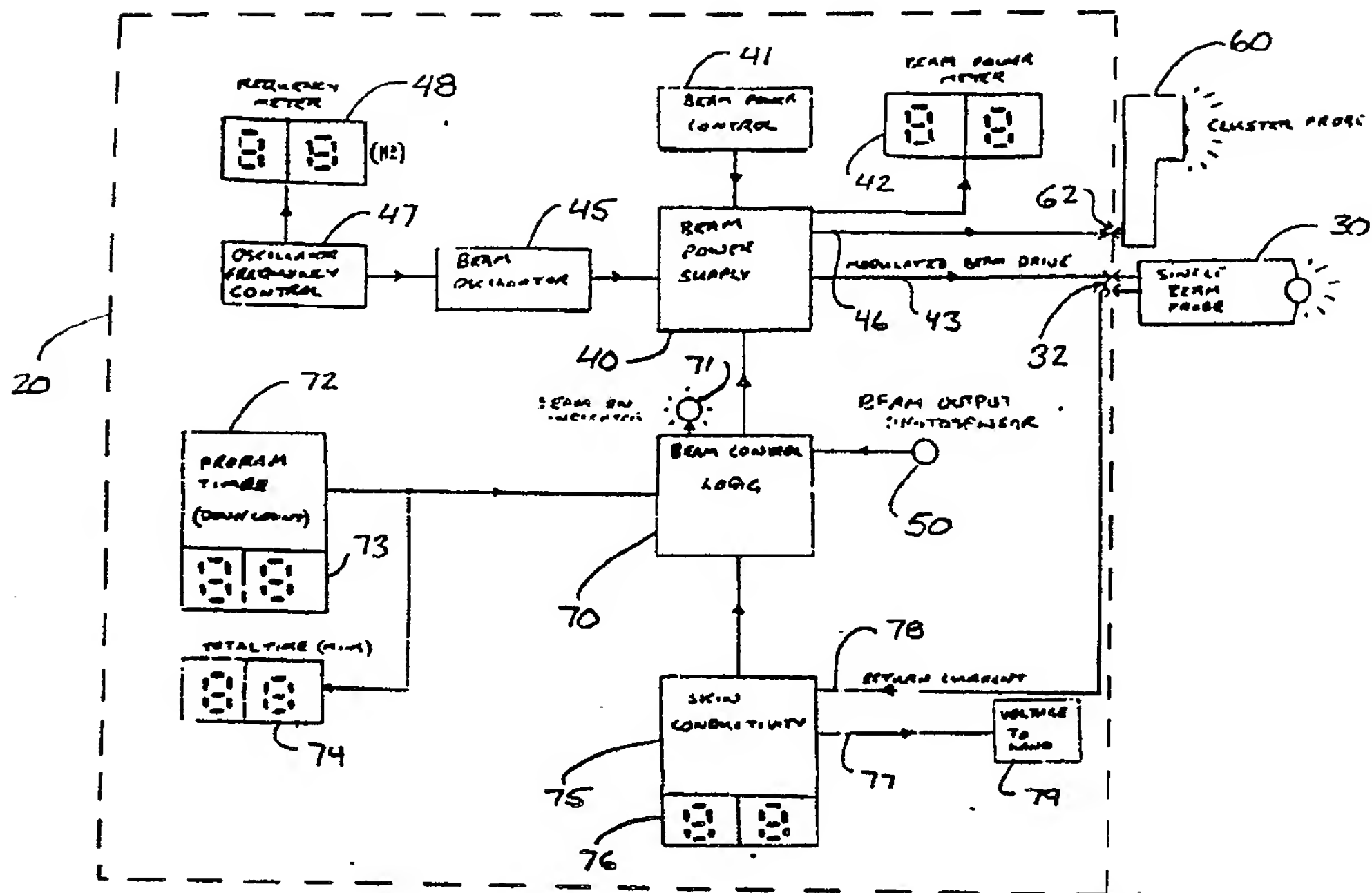


FIG. 4

A DEVICE FOR BIOSTIMULATION OF TISSUE AND METHOD FOR TREATMENT OF TISSUE

FIELD OF THE INVENTION

5 This invention relates to a new and improved device, method and system for biostimulation of tissue with low-power radiation, preferably substantially monochromatic radiation, having a plurality of wavelengths and having significant power densities over a treatment area.

BACKGROUND OF THE INVENTION

10 For many years, high-powered, highly focused lasers have been widely used to cut and destroy tissue in many surgical techniques. More recently, low-powered lasers, less sharply focused, which do not sever or destroy tissue have been found or are thought to effect numerous metabolic processes, including cell
 15 division, cyclic-AMP metabolism, oxidative phosphorylation, hemoglobin, collagen and other protein synthesis, leukocyte activity, tumor growth, production of macrophage cells and wound healing. See, for example, Karu and Letokhov "Biological Action of Low-Intensity Monochromatic Light in the Visible Range" in Laser Photobiology and Photomedicine, ed. Martellucci, p. 57-66 (Plenum Press 1985); Passarella, et al., "Certain
 20 Aspects of Helium-Neon Laser Irradiation on Biological Systems in Vitro" in Laser Photobiology and Photomedicine, ed. Martellucci p. 67-74 (Plenum Press 1985); see generally, Parrish, "Photomedicine: Potentials for Lasers. An Overview," in Lasers in Photomedicine and Photobiology, ed. Pratesi, p. 2-22 (Springer 1980); Giese, "Basic Photobiology and Open Problems" in Lasers in Photomedicine and Photobiology, ed. Pratesi, p. 26-39 (Springer 1980); Jori, "The Molecular Biology of Photodynamic Action"
 25 in Lasers in Photomedicine and Photobiology, ed. Pratesi, p. 58-66 (Springer 1980). Although the precise mechanism for these effects is not fully understood, it is believed to be tied to the activity of specific wavelengths of radiation in or near the range of visible light. Infrared laser radiation has been shown to increase ATP concentration and ATPase activity in living tissues. Bolognani, et al., "Effects of GaAs Pulsed Lasers on ATP Concentration and ATPase Activity In Vitro and In Vivo", International Cong. on Lasers in
 30 Medicine and Surgery, p. 47 (1985).

Radiation sources operating in or near the range of visible light, including lasers, emit photons which may interact with biological molecules to produce photochemical reactions and subsequent biologic effects. Photochemical and photobiological events at the atomic level depend upon the wavelength of radiation used to cause such events and occur without regard to the source of photons. However, the molecular effects,
 35 kinetics and products can be quantitatively and qualitatively altered one or more by other properties of radiation sources, e.g., monochromaticity, coherence and high power and energy density.

Most forms of photoexcitation are "quantum specific," i.e., excitation will only occur if a bundle of energy of a precise quantity is present to excite a given molecule or part of a molecule. A photon has energy E according to the formula:

$$E = h \times f = \frac{h \times c}{\text{wavelength}}$$

45 where f is frequency, h is Planck's constant and c is the speed of light. If a photon having a quantum of too little or too much energy is directed at a target molecule, it may not be absorbed; the photon must be of an exact energy to have an effect.

Only radiation which is absorbed has photochemical effects. X-rays, gamma rays and other absorbed
 50 high-energy photons affect human tissues by relatively indiscriminate ionization of molecules. The ionized molecules are highly reactive and covalent bonds may be broken or formed. Infrared photons excite specific vibrational or rotational modes in specific target molecules. The quantum of energy required to produce vibrational or rotational excitation is dependant on the character (e.g., double bond vs. ring structure) and location (e.g., near an electrophilic group vs. near a nucleophilic group) of the molecule. While it is believed that infrared photons may affect specific biological processes or transformations, the

most significant biological effect of these wavelengths is probably the heating caused by dissipation of the vibrational and rotational energy, which can significantly effect biological reactions in the vicinity of the dissipating molecule. The energy of photons in the ultraviolet and visible wavelengths causes electronic excitation of specific chromophores (i.e., molecules that absorb a photon of a given wavelength and use the energy to cause transition of an electron to a higher energy state). The decay of these stimulated molecules can then lead to specific reactions, including emission of a new photon, transfer of an electron or dissipation of heat.

In the past it has been difficult, however, to expose more than the first few layers of human skin or tissue to visible (400-700 nm) and ultraviolet (200-400 nm) radiation. Pigments and other molecules in the outer layers of skin are known to absorb the majority of visible and ultraviolet radiation, as shown in Figs. 1-3. Table 1 summarizes the approximate penetration of various wavelengths of radiation into the skin.

Table 1

Approximate Depth of Penetration of Optical Radiation in Fair Caucasian Skin to a Value of $1/e$ (37%) of the Incident Energy Density	
Wavelength, nm	Depth, nm
250	2
280	1.5
300	6
350	60
400	90
450	150
500	230
600	550
700	750
800	1200
1000	1600
1200	2200

As shown in Fig. 3, no ultraviolet radiation and approximately only 5% of most visible radiation penetrates to the subcutaneous layer of the skin. As a result, applying visible and ultraviolet radiation to the skin has little or no effect upon target molecules in lower layers that would become stimulated if exposed to those wavelengths of radiation.

While higher powered radiation sources can deliver greater energy to deeper layers, it is undesirable to directly expose tissue to large amounts of ultraviolet radiation due to the adverse effects of such radiation upon some molecules and cellular functions, e.g., DNA can be "mutated" by ultraviolet radiation.

It would therefore be desirable to provide a safe device and method for biostimulation of tissue that will stimulate biological processes affected by visible red and infrared radiation and also stimulate biological processes in lower layers of tissue that are affected by ultraviolet and visible radiation and would normally be inaccessible to radiation applied to the surface of the tissue because of the absorption of visible and ultraviolet radiation by skin pigments and other molecules.

SUMMARY OF THE INVENTION

A device for biostimulation of tissue is disclosed comprising an array of substantially monochromatic radiation sources of high power density and a plurality of wavelengths, preferably of at least three different wavelengths. The radiation sources are arranged within the array such that radiation of at least two different

wavelengths passes directly or indirectly through a single point located within the treatment target tissue. The radiation sources are preferably laser diodes, superluminous diodes or similar light-emitting diodes. A method of treatment of tissue comprising exposing the treated tissue to such a device is also disclosed. The device for biostimulation of tissue may be included within a system with a control panel, a power source, means for varying radiation pulse frequency, means for varying radiation pulse duration, means for timing the period of treatment, means for measuring the conductivity of the treatment target tissue, means for measuring the optical power emitted by the radiation sources and/or means for detecting emissions from the radiation sources.

It is an object of the present invention to provide a device and method for low power radiation for biostimulation of tissue that can deliver higher energy densities and a greater number of potentially biostimulative photons to deeper tissue layers.

It is another object of the invention to provide a device and method for biostimulation of tissue with multiple wavelengths of radiation.

It is a further object of the invention to provide a device and method for biostimulation of tissue utilizing semiconductor laser, superluminous or light emitting diodes as sources for low-power radiation in the infrared, visible and/or ultraviolet frequency ranges.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1 is a graph summarizing the ultraviolet absorption spectra of major epidermal chromophores: DOPA-melanin, 1.5 mg% in H₂O; urocanic acid 10⁻⁴ M in H₂O; calf thymus DNA, 10 mg% in H₂O (pH 4.5); tryptophan 2 x 10⁻⁴ M (pH 7); tyrosine, 2 x 10⁻⁴ (pH 7). [From Pratesi and Sacchi, Eds., Lasers in Photomedicine and Photobiology, p. 165 (Springer 1980)].

Fig 2 is a graph summarizing the visible light absorption spectra of major human skin pigments. Parentheses indicate solvents used. [From Pratesi and Sacchi, Eds., Lasers in Photomedicine and Photobiology, p. 172 (Springer 1980)].

Fig. 3 is a pictorial and graphic representation of the relative penetration of various radiation wavelengths into human skin. [From D. Slimey and M. Wolbarsht, Safety With Lasers and Other Optical Sources (1980)].

Fig. 4 is a function block diagram of the device and system of the present invention.

Fig. 5 is a side view of a cluster probe or radiation source array used in the present invention.

Fig. 6 is a plan view of a radiation source array used in the present invention.

Fig. 7 is a plan view of another radiation source array comprising an alternative embodiment of the present invention.

Fig. 8 is a plan view of another radiation source array comprising an alternative embodiment of the present invention.

Fig. 9 is a simplified schematic view of the radiation beams of three diodes as used in the present invention impinging on a treatment tissue target.

DETAILED DESCRIPTION OF THE INVENTION

A. System Overview.

The block diagram of Fig. 4 shows the overall structure of the device and system of the present invention. A control unit 20 contains both controls and displays to read out control settings and measured values. To this control unit 20 a single beam probe 30 and a cluster probe 60 may be connected at plug-in connections 32 and 62, respectively. Central to the control unit 20 are a beam power supply 40 and, connected thereto a beam control logic unit 70. The beam power supply has two output lines 43 and 46. Output line 46 leads to plug-in connection 62 for the cluster probe 60. Output line 43 leads to plug-in connection 32 for single beam probe 30.

Beam power control 41 is connected to beam power supply 40 to permit setting of the beam power level. Beam power meter 42 is connected to the beam power supply 40 to show the power level being delivered.

To provide radiation beams modulated in pulses of various frequencies, a beam oscillator 45 is connected to the beam power supply 40. The beam oscillator 45 is controlled by an oscillator frequency control 47 connected to the beam oscillator 45. A frequency meter 48 connected to the oscillator frequency control 47 provides display of the selected beam modulation frequency. If pulse duration modulation is desired as a further form of modulation, this can be accomplished by additional refinements of the beam oscillator 45 and its corresponding oscillator frequency control 47.

The beam control logic unit 70 is, as previously noted, connected to the beam power supply 40. An indicator light 71 associated with the unit shows when the beam power is on. This is useful because the beam wavelengths being used may not be visible and treatment time, as well as power, is an important variable ($E = P \times T$). As a further check that the unit is functioning, the invention provides a beam output photosensor 50 connected to the beam control logic unit 70 described below). This photosensor 50 is sensitive to the frequencies of radiation produced by the unit and provides a signal when it receives radiation. To aid control of treatment time, a down-counting program timer 72 with a display 73 that follows the down count is connected to the beam control logic unit 70. A further display 75, also connected to the beam control logic unit 70, provides a display of total beam on-time (in minutes).

For some uses of the invention, it is desirable to locate body points of high skin conductivity. (These usually correspond to pain trigger points of inflammatory areas, as increased temperatures will raise skin conductivity.) The present invention does this with a skin conductivity measuring module 75 connected to beam control logic unit 70, with associated display 76. This module 75 delivers a small current (microamps) via a lead 77 connected to an electrode 79 held in the hand of a patient. The single beam probe 30 is used to form a return path from a selected skin location, utilizing lead 78 as a return current path (from plug-in connection 32) to the skin conductivity measuring module 75. If desired, the skin conductivity measurement can be used as a trigger for the beam control logic unit 70; that is, the beam control logic unit 70 can be set to enable a beam only when a preselected skin conductivity level is present. When this level is chosen to be very low, the beam is enabled whenever the return path probe is in contact with a skin area to be treated.

The present invention utilizes, as noted above, radiation in or near the infrared spectrum (above 700 nm), the visible light spectrum (400-700 nm) and the ultraviolet spectrum (200-400 nm). For convenience in the following, the radiation comprising the beams produced by the present invention may be referred to as "light", although it may be in the visible or ultraviolet spectra or in other nearby spectra.

The single beam probe 30 of the present invention is shaped like a fat pencil (Fig. 4). It emits radiation of a single frequency and is therefore of limited interest in connection with the present invention. The gravamen of the invention is use of multiple radiation sources of multiple frequencies. This radiation is emitted by the multiple radiation sources contained in cluster probes 60 used with the present invention.

Fig. 5 shows a side view of a cluster probe 60, having a thin cylindrical handle 61 and a thicker cylindrical head 62. Figs. 6 through 8 show three patterns of radiation sources that can be contained within the cylindrical head 62. The radiation is emitted from a plane very near one end-face of the cylinder 62. Figs. 6-8 show head-on views of several end-faces. As will be described below, the end-faces involve various configurations of radiation sources. Each of these configurations provides a different mix of radiation source frequencies and a somewhat different geometric configuration. These configurations accordingly produce different "mixtures" of radiation frequencies in the target tissue and different power densities.

The sources of light or radiation in each of the cluster probes 60 in Figs. 6-8, showing particular forms of radiation arrays, are semiconductor light emitting devices, e.g., light emitting diodes (LED'S). Two particular types of LED'S have been found most useful for purposes of the present invention: laser diodes and superluminous diodes. Laser diodes produce a beam of light or radiation that is essentially monochromatic, is sharply collimated and is coherent. That is, they produce light almost exclusively at one frequency (unless they are multi-mode type lasers) and the light beam has a small angle of divergence. Superluminous diodes are also used. These are similar but lack the coherence and the sharply monochromatic characteristics of laser diodes; yet they produce highly directional light that is also limited in its frequency range.

A number of commercially available semiconductor laser diodes exist. Typical of these are those described in "Optoelectronic Devices Data Book" published by Hitachi, Ltd. (September, 1984).

It has been found, however, that semiconductor laser diodes having somewhat higher power outputs and narrower beam divergence and spectral widths than the most widely manufactured components are also available and may enhance the advantages of the present invention. Not all frequencies are available in the range from ultraviolet through visible to infrared radiation. But enough are available that some selection among frequencies can be made. Among low power lasers suitable for the present invention, the laser

power rating (continuous power) of individual diodes is generally in the range from 5-500 milliwatts (mW). Laser diodes are available with continuous wave emission capability and as devices that must be pulsed. The following laser diode specifications have been found useful for the present invention:

1. Double Heterostructure Continuous Wave Laser Diode GaAlAs

5 Wavelength: 750, 780, 800, 810, 820, 830, 850nm
 Peak Power Output: 5mW - 500 mW (Class 3B)
 Beam Divergence: 60° parallel, 12° perpendicular (typical, variable according to manufacturing method)
 Polarisation: Linear 90-100%
 Spectral Width: 0.02nm-1.0nm

10 2. Single Heterostructure Pulsed Laser Diode GaAs

Wavelength: 904nm
 Peak Power Output: 70W
 Avg. Power: 0.15-15mW (frequency dependent)
 Max. Pulse Duration: 200 microseconds.
 15 Beam Divergence: 6°-15° parallel, 15°-30° perpendicular
 Spectral Width: less than 3.5nm

3. Double Heterostructure Pulsed Laser Diode GaAs/GaAlAs Wavelength: 850-904nm

Peak Power: 325mW
 Average Power: 40-80mW
 20 Faxed Duty Factor ($T_w \times F_n$): 15%; $f = 300\text{KHz}$, $T_w = 500$ microseconds.
 Beam Divergence: 6°-15° parallel, 15°-30° perpendicular
 Spectral Width: 2-3nm

As best seen in Fig. 6, the preferred embodiment of the cluster probe 60 of the present invention
 25 comprises an array 80 of five 660 nm superluminescent diodes 166, one 820 nm laser diode 182, ten 880
 superluminescent or laser diodes 188 and five 950 superluminescent diodes 195. The diodes are arranged in a
 planar array such that the 820 nm diode 182 is positioned in the center of the array, five of the ten 880 nm
 diodes 188 are evenly positioned about the circumference of a circle of about 9.5 mm radius from the
 center of the array, the five 660 nm diodes 166 are evenly positioned about the circumference of a circle of
 30 about 18 mm radius from the center of the array such that a radial line from the center of the array to each
 660 nm diode 166 bisects the arc between two of the innermost 880 nm diodes 188, the 950 nm diodes
 195 are evenly positioned about the circumference of a circle of about 27 mm radius from the center of the
 array such that a radial line from the center of the array to each 950 nm diode 195 passes through the
 center of one of the innermost 880 nm diodes 188, and the remaining five 880 nm diodes 188 are evenly
 35 positioned about the circumference of a circle of about 27 mm radius from the center of the array such that
 a radial line from the center of the array to each outer 880 nm diode 188 passes through the center of one
 of the 660 nm diodes 166.

In an alternative embodiment shown in Fig. 7, the 820 nm diode, 182 is positioned in the center of the
 array 90, ten 880 nm diodes 188 are evenly positioned about the circumference of a circle of about 10.5
 40 mm radius from the center of the array, and five 660 nm diodes 166 and five 950 nm diodes 195 are
 alternately positioned and evenly spaced about the circumference of a circle of about 17 mm radius from the
 center of the array, such that a radial line from the center of the array to each 660 nm or 950 nm diode,
 166, 195 respectively, bisects the arc between two of the 880 nm diodes 188.

Another alternative embodiment of the cluster probe 60 of the present invention, shown in Fig. 8,
 45 comprises an array 100 of ten 660 nm superluminescent diodes 166, one 820 nm laser diode 182, ten 880 nm
 superluminescent or laser diodes 188, and ten 950 nm superluminescent diodes 195. The diodes are arranged in
 a planar array such that the single 820 nm diode 182 is positioned in the center of the array, ten 880 nm
 diodes 188 are evenly positioned about the circumference of a circle of about 9.5 mm radius from the
 center of the array, ten 660 nm diodes 166 are evenly positioned about the circumference of a circle of
 50 about 18 mm radius from the center of the array such that a radial line from the center of the array to each
 660 nm diode 166 bisects the arc between two of the 880 nm diodes 188, and ten 950 nm diodes 195 are
 evenly positioned about the circumference of a circle of 27 mm radius from the center of the array, such
 that a radial line from the center of the array to each 950 nm diode 195 passes through the center of one of
 the 880 nm diodes 188.

55

B. Theory of Operation

The diodes within the array of each embodiment are closely arranged such that although the radiation they produce is emitted in a narrow beam, their beams overlap a short distance away from the surface of the cluster probe 60. Thus, as can be seen in Fig. 9, two or more wavelengths of radiation from the array 60 simultaneously pass through some point in the tissue 100 being stimulated. In Fig. 9, the divergence of each radiation beam is schematically shown for three radiation sources 182, 188 and 195 assumed to line
 5 along a single line. Radiation source 182 is assumed to have a beam divergence of six degrees, while radiation sources 188 and 195 are assumed to have beam divergence of 15 degrees. No other optical effects such as reflection, refraction or scattering are assumed. Fig. 9 shows that the beams will begin to overlap after they have traveled a few centimeters from the face of the cluster array 60. Obviously, overlap
 10 occurs even sooner when the diodes are more closely spaced.

When tissue is stimulated with these arrays of radiation sources, a cumulative, and sometimes synergistic, effect is believed to occur, which is not seen when a single wavelength is used. It has been proposed that this effect is due, in part, to the "mixing" of photons of different wavelengths which results in three types of "two-photon events". In the first type, two different adjacent molecules are excited by
 15 different wavelength photons. In the second type, two different parts of the same molecule are excited by different wavelength photons. Both of these types of events produce excited states that would not be possible if the same molecules were stimulated with photons of only one wavelength. These "new" excited states may also make the molecule(s) involved more susceptible to certain types of decay, dissipation and reaction with each other or other unexcited molecules.

In the third type of two-photon event, a single electron is simultaneously excited by two coinciding photons of different wavelengths. The high density of photons produced by devices of small emitting surface area of the present invention enhances the probability of this type of two-photon event occurring. Assuming that all of the simultaneously-presented energy is absorbed by an electron, the resultant quantum of energy delivered by two photons is equivalent to that of a photon of a much smaller wavelength. For
 25 example, for an 880 nm photon:

$$E_{880} = \frac{h \times c}{880 \text{ nm}}$$

30

For an 820 nm photon:

$$E_{820} = \frac{h \times c}{820 \text{ nm}}$$

35

Since the effective energy of both photons will be the sum of E_{880} and E_{820} :

$$E_{\text{effective}} = E_{880} + E_{820} = \frac{h \times c}{\text{effective wavelength}},$$

40

The effective wavelength is about one-half of the average of the two original wavelengths or, in this example, approximately 425 nm. In effect, the target molecule is stimulated as if it had been hit with a
 45 single 425 nm photon.

The third type of two-photon event is especially significant because 425 nm is a wavelength that would normally be absorbed by skin pigments and would not penetrate very deeply into the skin. By stimulating the tissue with photons at 880 nm and 820 nm the screening effect of the skin is avoided. In certain preferred and alternative embodiments diodes of four wavelengths are used, thus creating ten different two-
 50 wavelength combinations, resulting in ten effective wavelengths during the third type of two-photon event. The effective wavelengths range from 330 nm to 475 nm which approximately corresponds to the range of highest absorption by skin pigments as shown in Fig. 2.

As noted above, an array of radiation sources as used in the present invention may be comprised of laser, superluminous and similar light-emitting diodes. These types of diodes are all substantially monochromatic non-gaseous radiation sources. Continuous wave diodes are preferable, because they have a higher
 55 average available power than pulsed diodes. Appropriate diodes are available from several suppliers at wavelengths of 650 nm, 660 nm, 680 nm, 750 nm, 780 nm, 800 nm, 810 nm, 820 nm, 830 nm, 840 nm, 850 nm, 860 nm, 870 nm, 880 nm, 900 nm, 904 nm, 1100 nm, 1300 nm and 1500 nm. These radiation sources

are "substantially monochromatic," as that term is used throughout this specification and the appended claims, in that, in addition to emitting light or radiation at substantially one "main" wavelength, they also emit a significantly smaller amount of radiation at other wavelengths which are close, but not identical, to the "main" wavelength. A laser diode will emit at a "main" wavelength and a few peripheral wavelengths
 5 (corresponding to multiple resonances or off-axis modes) characterized by distinct narrow spikes in its wavelength spectrum. A superluminescent or other light-emitting diodes will emit at a "main" wavelength that is at the peak of a somewhat broader continuous band of wavelengths in a wavelength spectrum. By convention, the "main" wavelength is used to identify the diode (e.g., a "800 nm diode" will emit at a "main" wavelength of 800 nm and at some other peripheral wavelengths characteristic of the material from
 10 which the diode is made). It should be noted that the number of combinations of two wavelengths leading to possible two-photon events is increased dramatically by the existence of peripheral wavelengths associated with the "main" wavelength of each type of diode. The slight variations in wavelength can lead to virtually hundreds of two-wavelength combinations and, as a result, hundreds of effective wavelengths in the visible and ultraviolet spectra.

15 The present invention has as one objective the delivery of significant amounts of low-power radiation to deeper tissues. For this reason, the radiation sources, while low-powered, are relatively tightly-clustered. For the arrays shown in Figs. 6-8, the average power density at the plane of the array is in the range from about 10mW/cm² to about 40 mW/cm². Due to beam divergence, absorption, reflection, refraction, scattering and other similar effects, the average power density decreases with distance from the plane of the array either
 20 through air or into tissue. It should be noted, however, that due to the small radiation surface areas of some laser diodes, certain small areas near the plane of the array or at the surface of the treated tissue (when the cluster probe 60 is placed immediately adjacent the tissue) may have a power density of at least 120 mW/cm². Should it be found that higher energy densities yield enhanced biostimulative effects without undesirable side effects, even higher powered diodes and/or somewhat more densely clustered diodes can
 25 be utilized. Of course, the energy delivered to a given area of tissue is also a function of time of exposure. Accordingly, it is also useful to speak of an energy density provided per unit area, defined as the power density multiplied by the exposure time. By this formula, a sixty second exposure of tissue with a minimum power density of 120mW/cm² (which might be found to be a minimum exposure for some significant therapeutic result) could be described as of minimum treatment energy density of 7.2 Joules/cm².

30 In the preferred and alternative embodiments of present invention, the radiation sources can be modulated in pulses of different frequencies ranging from 2.28 Hz to 400 kHz, including 2.28 Hz, 4.56 Hz, 9.12 Hz, 16 Hz, 18.24 Hz, 36.48 Hz, 73 Hz, 146 Hz, 292 Hz, 700 Hz, 1000 Hz, 5 kHz and 300 kHz. This is done by means of the oscillator frequency control 47 mentioned above. Other frequencies could obviously be selected. As mentioned above, the beam oscillator 45 and its frequency control 47 can also provide
 35 pulse duration modulation for continuous wave radiation sources. Thus, for the same frequency a higher average power can be obtained according to the formula: $P \text{ (average)} = P \text{ (peak)} \times \text{Pulse duration} \times \text{Frequency}$.

40 2. Method of Treatment

The present invention also includes a method for treatment of tissue. The method involves exposing the tissue to a plurality of radiation sources of different wavelengths. More generally, the method of treatment of the present invention involves the simultaneous exposure of the tissue to at least three different
 45 wavelengths of radiation. Any embodiment of the device of the present invention, including but not limited to those previously described, can be used to perform this method of treatment. The array of radiation sources is preferably placed directly adjacent to or on the skin such that the plane of the radiation sources is close to or comes in contact with the outermost layer of skin. Because oils and other substances on the surface of the skin may cause absorption, refraction, reflection and/or diffraction of some wavelengths of
 50 radiation and thereby decrease radiation penetration, for effectiveness these should be removed before treatment.

Devices of the present invention have been used to treat various conditions in clinical settings. The results of those clinical applications as reported by several medical doctors and physiotherapists in the United Kingdom are summarized in the following examples.

55

Example 1

A patient had a thirteen year history of extreme pain in the right big toe after engaging in sports activities. Upon examination, the patient was found to have a congenital Hallux Valgus or chronic "bunion". The sore toe was treated with a multi-diode biostimulation device of the present invention (660 nm, 820nm 880 nm, 950 nm) for a period of ten minutes. The patient experienced immediate relief of all pain and was
 5 able to engage in sports activities the day after treatment.

Example 2

10

A patient experienced post plaster pain for two weeks following an operation for Hallux Valgus on the left foot. Examination revealed pitting edema of the forefoot, slight swelling of the ankle and limited movement of the foot. The patient was treated daily for five minutes with a multi-diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm). Treatment continued for five days. Swelling
 15 decreased after each treatment. After the third treatment, the foot was pain free, but still slightly swollen. Upon completion of treatment, all symptoms had been relieved.

Example 3

20

A 24 year-old patient experienced pain after surgery to repair a ruptured left anterior cruciate ligament. The patient was treated twice daily with a multi-diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm) for a period of 4 minutes, 30 seconds. After treatment, the patient was pain
 25 free and showed signs of good tissue repair.

Example 4

30

A 38 year-old patient had experienced chronic fibrositis in the neck for 18 years. The patient was treated daily for two days with a 21 diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm) for a period of 4 minutes, 30 seconds. Each treatment was followed by treatment by treatment with a 15 mW 850 nm single diode probe for two minutes. After treatment, the patient experienced 98% pain
 35 relief.

Example 5

40

A 35 year-old patient had experienced muscle spasms in the lower back. The patient was treated twice in a single day with a multi-diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm) for a period of 4 minutes, 30 seconds. After treatment, the patient experienced total pain relief.

45

Example 6

A 33 year-old patient had experienced pain in the head of his fibula secondary to a knee injury in which
 50 the patient sustained a torn medial meniscus and ruptured anterior cruciate. The meniscus had been removed. The pain radiated down the leg and was associated with limitation of knee flexion. The patient was treated six times with a 660 nm single diode probe for a period of 4 minutes followed by treatment with a multi-diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm) for a period of 2 minutes. Laser treatment was used in conjunction with mobilizations. After treatment, the patient
 55 experienced relief of virtually all pain and regained full range of knee flexion.

Example 7

5 A 21 year-old patient had experienced an inflamed gleuteal bursa. The patient was treated three times with a diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm). After treatment, the patient showed no further pain and no reoccurrence.

Example 8

10

A 35 year-old patient had experienced a non-healing skin ulcer for 3 years following a motorcycle accident. The patient was treated 10 times with a multi-diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm). After treatment, the tissue showed increased granulation (+ +) and the ulcer had decreased in size and looked healthier.

15

Example 9

20 A 70 year-old patient had experienced a diabetic ulcer following an above-knee amputation. The lateral third of the ulcer was treated with a 830 nm single diode probe and a multi-diode biostimulation device of the present invention (660 nm, 820 nm, 880 nm, 950 nm) for a period of 90 seconds each. After treatment, increased healing, granulation and de-sloughing were observed.

25 Preliminary indications are that the method and apparatus of the invention may be used widely for therapeutic purposes, for example, to treat inflammations, wounds, burns, chronic ulcerations including diabetic ulcers, deficient circulation, pain, nerve degeneration, eczema, shingles, infection, scars, acne, bone fractures, muscle and ligament injuries, arthritis, osteo-arthritis, rheumatoid arthritis, skin grafts, gingival irritation, oral ulcers, dental pain and swelling, cellulitis, stretch marks, skin tone, alopecia areata, trigeminal neuralgia, herpes, zoster, sciatica, cervical erosions and other conditions.

30 From the foregoing, it will be obvious to those skilled in the art that various modifications in the above-described method and apparatus can be made without departing from the spirit and scope of the invention. Accordingly, the invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. Present embodiments, therefore, are to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than
35 by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

Because of the nature of light and the optical properties of tissue, power density from a single light source obtained at subcutaneous tissue is attenuated. However, when multiple crossing or overlapping beams of light are present, regions of added power density occur in the subcutaneous tissue which enable
40 a therapeutic threshold to be achieved. The occurrence of these regions of added power density or "hot spots" enables sufficient energy density to be achieved within an acceptably short exposure time.

It has also been found as a result of laboratory research that certain cells, e.g. macrophages, when exposed to light at particular wavelengths, release a number of wound factor chemicals which can assist in the repair of damaged tissue. For example, light at 820 (laser diode), 660, 870 nm (super luminous diode)
45 released factors that helped the proliferation of fibroblasts significantly above control levels in in vito culture. Monochromatic light at 880 nm (superluminous diode) released factors that inhibited fibroblast proliferation, which may be significant when uncontrollable fibroblast proliferation needs to be prevented e.g. to prevent keloids scar tissue formation after burns. It has been suggested that the protein coating of cells may be involved and that different cells e.g. fibroblasts, T-cells, B-cells may each react at a different wavelength or
50 set of wavelengths provided that there is more than a threshold energy density available and targeted to the cell. When a device according to the invention is used to irradiate tissue, cells along the path of the beams will react according to their sensitive wavelengths. Cells located at deeper strata may not respond to a single wavelength because of power density attenuation, but in the regions of the overlapping beams or "hot spots" or similar or different wavelengths the energy density threshold can be achieved and a useful
55 therapeutic result can be obtained. The possibility of 2-photon events and the effective new wavelengths created allows more kinds of cells to be targeted including possibly neural cells.

Claims

1. A device for biostimulation of tissue comprising:
 an array of substantially monochromatic radiation sources, said array comprising:
 5 at least one such radiation source providing a first wavelength less than 830 nm;
 at least one such radiation source providing a second wavelength greater than or equal to 830 nm and less than 900 nm; and
 at least one such radiation source providing a third wavelength greater than or equal to 900 nm;
 said radiation sources being arranged such that at least two radiation wavelengths among said first, second
 10 and third wavelengths simultaneously pass directly or indirectly through a single point located within said tissue.
2. The device for biostimulation of tissue of Claim 1, wherein:
 (a) said radiation sources are selected from the group consisting of superluminous diodes and laser diodes; and/or
 15 (b) said first wavelength is selected from the group consisting of 650 nm, 660 nm, 680 nm, 750 nm, 780 nm, 800 nm, 810 nm and 820 nm;
 said second wavelength is selected from the group consisting of 830 nm, 840 nm, 850 nm, 860 nm, 870 nm, and 880 nm; and
 said third wavelength is selected from the group consisting of 900 nm, 904 nm, 950 nm, 1100 nm, 1300 nm
 20 and 1500 nm; and/or
 (c) said first wavelength is selected from the group consisting of 660 nm and 820 nm;
 said second wavelength is selected from the group consisting of 875 nm and 880 nm; and
 said third wavelength is 950 nm.
- 25 3. The device for biostimulation of tissue of Claim 2, wherein said radiation sources are modulated at pulse frequencies selected from within the range of 2.28 Hz to 400 kHz.
4. The device for biostimulation of tissue of Claim 3, wherein said pulse frequencies are selected from the group consisting of 2.28 Hz, 4.56 Hz, 9.12 Hz, 16 Hz, 18.24 Hz, 36.48 Hz, 73 Hz, 146 Hz, 292 Hz, 700 Hz, 1000 Hz, 5 kHz and 300 kHz.
- 30 5. The device for biostimulation of tissue of Claims 2, 3 or 4, wherein said array comprises:
 five 660 nm superluminous diodes;
 one 820 nm laser diode;
 ten 880 nm superluminous or laser diodes; and
 five 950 nm superluminous diodes.
- 35 6. The device for biostimulation of tissue of Claim 5, wherein:
 said 820 nm diode is positioned in the center of said array;
 said 880 nm diodes are evenly positioned about the circumference of a circle of 10.5 mm radius from the center of said array; and
 said 660 nm diodes and 950 nm diodes are alternately positioned and evenly spaced about the
 40 circumference of a circle of 17 mm radius from the center of said array such that a radial line from the center of said array to each of said 660 nm or 950 nm diodes bisects the arc between two of said 880 nm diodes.
7. The device for biostimulation of tissue of Claim 6, wherein:
 said 820 nm diode is positioned in the center of said array;
 45 five of said 880 nm diodes are evenly positioned about the circumference of a circle of 10.5 mm radius from the center of said array;
 said 660 nm diodes are evenly positioned about the circumference of a circle of 17 mm radius from the center of said array such that a radial line from the center of said array to each of said 660 nm diodes bisects the arc between two of said 880 nm diodes in said first set;
 50 said 950 nm diodes are evenly positioned about the circumference of a circle of 17 mm radius from the center of said array such that a radial line from the center of said array to each of said 950 nm diodes passes through the center of one of said 880 nm diodes in said first set; and
 the remaining five of said 880 nm diodes are evenly positioned about the circumference of a circle of 27 mm radius from the center of said array such that a radial line from the center of said array to each of said
 55 880 nm diodes passes through the center of one of said 660 nm diodes.

8. The device for biostimulation of tissue of Claim 2, wherein said array comprises:

ten 660 nm superluminous diodes;
 one 820 nm laser diode;
 ten 880 nm superluminous or laser diodes; and
 5 ten 950 nm superluminous diodes.

9. The device for biostimulation of tissue of Claim 8, wherein:

said 820 nm diode is positioned in the center of said array;
 said 880 nm diodes are evenly positioned about the circumference of a circle of 9.5 mm radius from the center of said array;

10 said 660 nm diodes are evenly positioned about the circumference of a circle of 18 mm radius from the center of said array such that a radial line from the center of said array to each of said 660 nm diodes bisects the arc between two of said 880 nm diodes; and

said 950 nm diodes are evenly positioned about the circumference of a circle of 27 mm radius from the center of said array such that a radial line from the center of said array to each of said 950 nm diodes
 15 passes through the center of one of said 880 nm diodes.

10. A device for biostimulation of tissue comprising:

an array of substantially monochromatic radiation sources, said array comprising:

at least one such radiation source providing a first wavelength less than 830 nm;

20 at least one such radiation source providing a second wavelength greater than or equal to 830 nm and less than 875 nm;

at least one such radiation source providing a third wavelength greater than or equal to 875 nm and less than 900 nm; and

at least one such radiation source providing a fourth wavelength greater than or equal to 900 nm;

25 said radiation sources being arranged such that at least two radiation wavelengths among said first, second, third and fourth wavelengths simultaneously pass directly or indirectly through a single point located within said tissue.

11. The device for biostimulation of tissue of Claim 10, wherein said radiation sources are selected from the group consisting of superluminous diodes and laser diodes.

12. The device for biostimulation of tissue of Claim 11, wherein:

30 said first wavelength is selected from the group consisting of 650 nm, 660 nm, 680 nm, 750 nm, 780 nm, 800 nm, 810 nm and 820 nm;

said second wavelength is selected from the group consisting of 830 nm, 840 nm, 850 nm, 860 nm and 870 nm;

said third wavelength is 880 nm; and

35 said fourth wavelength is selected from the group consisting of 900 nm, 904 nm, 950 nm, 1100 nm, 1300 nm and 1500 nm.

13. A device for biostimulation of tissue comprising:

an array of substantially monochromatic light-emitting diodes, said array comprising:

at least one diode providing a first wavelength less than 800 nm; and

40 at least one diode providing a second wavelength greater than or equal to 800 nm;

said diodes being arranged such that radiation of said first and second wavelengths simultaneously passes directly or indirectly through a single point located within said tissue.

14. The device for biostimulation of tissue of Claim 13, wherein:

45 said first wavelength is selected from the group consisting of 650 nm, 660 nm, 680 nm, 750 nm and 780 nm; and

said second wavelength is selected from the group consisting of 800 nm, 810 nm, 820 nm, 830 nm, 840 nm, 850 nm, 860 nm, 870 nm, 880 nm, 900 nm, 904 nm, 950 nm, 1100 nm, 1300 nm and 1500 nm.

15. A device for biostimulation of tissue comprising:

50 an array of substantially monochromatic light-emitting diodes, said diodes being arranged in a single plane and emitting an average power density at said plane of at least 10 mW/cm².

16. A device for biostimulation of tissue comprising:

an array of substantially monochromatic light-emitting diodes, said diodes being arranged so as to provide a power density of at least 120 mW/cm² at some point on the surface of said tissue.

17. A device for biostimulation of tissue comprising:

55 an array of substantially monochromatic non-gaseous continuous wave radiation sources, said radiation sources being arranged in a single plane and emitting an average power density at said plane of at least 10 mW/cm².

18. A device for biostimulation of tissue comprising:
 an array of substantially monochromatic non-gaseous continuous wave radiation sources, said radiation sources being arranged so as to provide a power density of at least 120 mW/cm² at some point on the surface of said tissue.

5 19. A system for biostimulation of tissue comprising:
 a biostimulation device comprising:
 an array of substantially monochromatic radiation sources, said array comprising:
 at least one such radiation source providing a first wavelength less than 830 nm;
 at least one such radiation source providing a second wavelength greater than or equal to 830 nm and less
 10 than 900 nm; and
 at least one such radiation source providing a third wavelength greater than or equal to 900 nm;
 said radiation sources being arranged such that at least two radiation wavelengths among said first, second
 and third wavelengths simultaneously pass directly or indirectly through a single point located within said
 tissue; and
 15 means in communication with said array for providing power to said radiation sources such that each of said
 radiation sources emits radiation at its characteristic wavelength.

20. The system for biostimulation of tissue of Claim 2, wherein said system further comprises:
 (a) means in communication with said power-providing means for modulating the output of said
 sources with pulses and varying the modulation pulse frequency of said radiation sources; and/or
 20 (b) means in communication with said power-providing means for varying the pulse duration of said
 radiation sources; and/or
 (c) means in communication with said power-providing means for timing the period that power is
 provided to said radiation sources; and/or
 (d) means in communication with said power-providing means for measuring the electrical conductiv-
 25 ity of said tissue; and/or
 (e) means in communication with said array for measuring the optical power emitted by said radiation
 sources; and/or
 (f) means in communication with said control panel for detecting radiation from said radiation sources;
 and
 30 indicator means connected to said detecting means for indicating that radiation is being emitted from said
 radiation sources.

21. A system for biostimulation of tissue comprising:
 a biostimulation probe comprising:
 35 an array of substantially monochromatic radiation sources, said array comprising:
 at least one such radiation source providing a first wavelength less than 830 nm;
 at least one such radiation source providing a second wavelength greater than or equal to 830 nm and less
 than 900 nm; and
 at least one such radiation source providing a third wavelength greater than or equal to 900 nm;
 40 said radiation sources being arranged such that at least two radiation wavelengths among said first, second
 and third wavelengths simultaneously pass directly or indirectly through a single point located within said
 tissue;
 means in communication with said array for providing power to said radiation sources such that each of said
 radiation sources emits radiation at its characteristic wavelength;
 45 means in communication with said power-providing means for modulating the pulse frequency of said
 radiation sources;
 means in communication with said power-providing means for varying the pulse duration of said radiation
 sources;
 means in communication with said power-providing means for timing the period that power is provided to
 50 said radiation sources;
 means in communication with said array for measuring the electrical conductivity of said tissue;
 means in communication with said power-providing means for measuring the optical power emitted by said
 radiation sources; and
 means in communication with said control panel for detecting emissions from said radiation sources.

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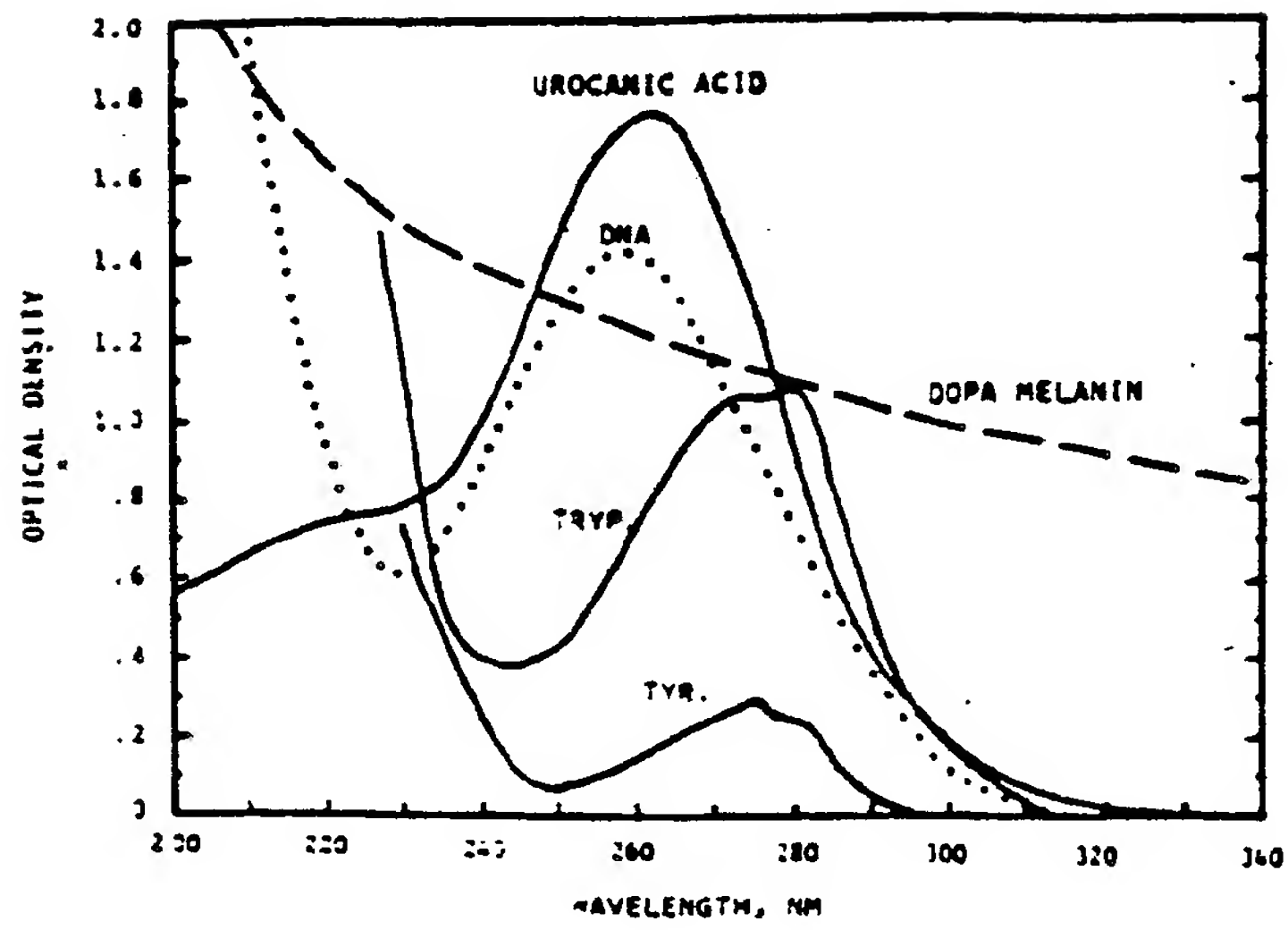


FIG. 1

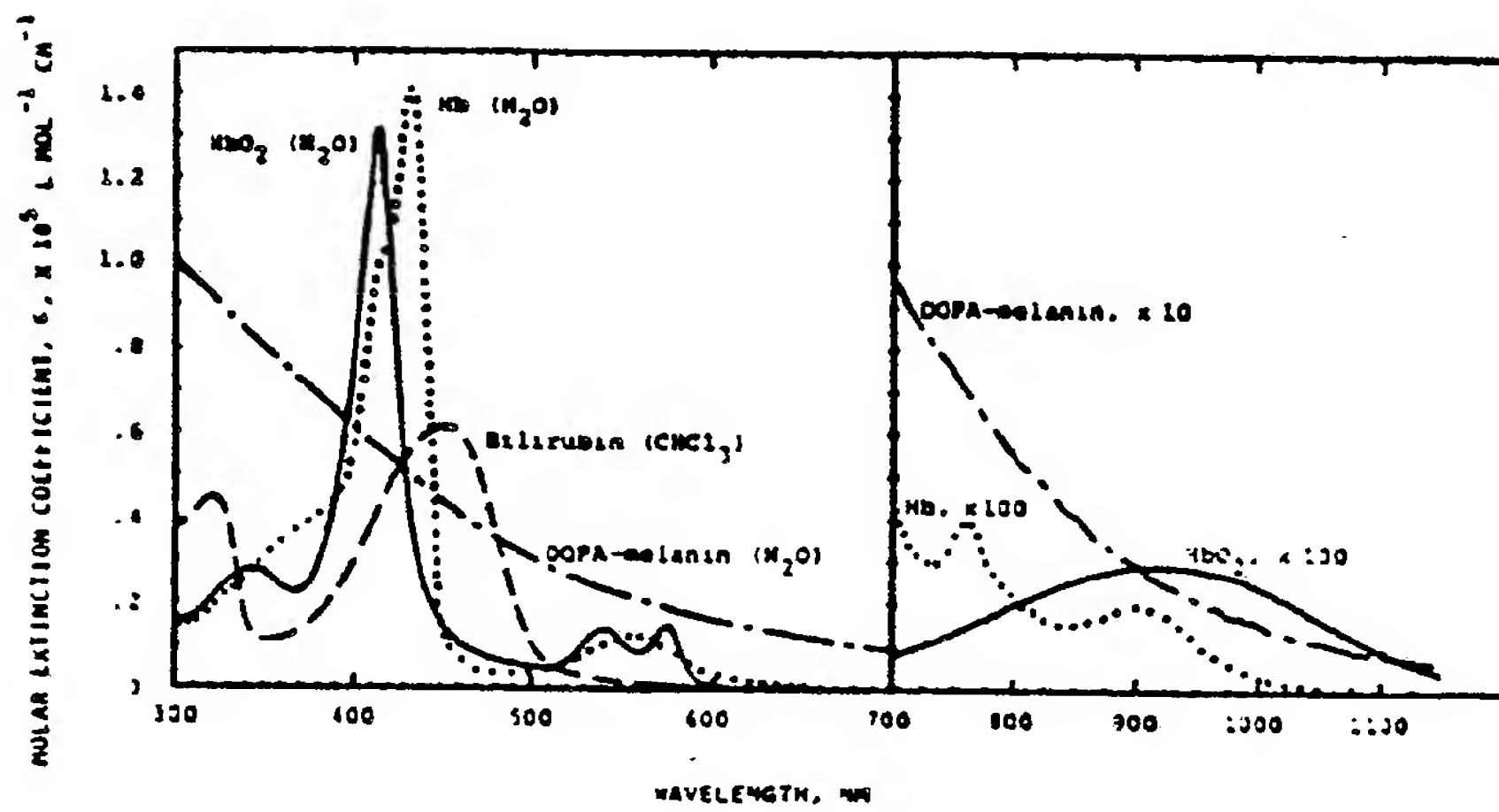


FIG. 2

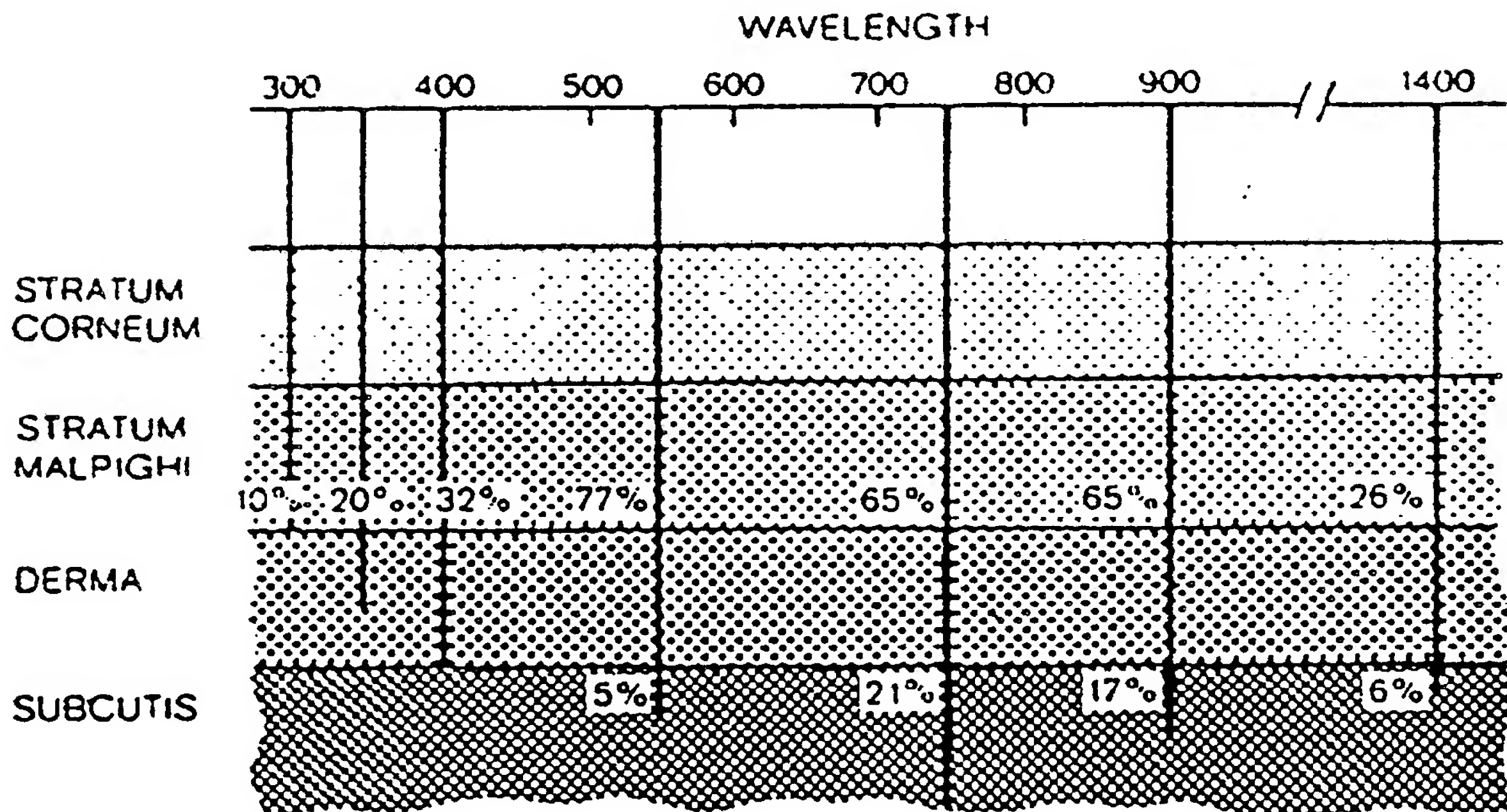
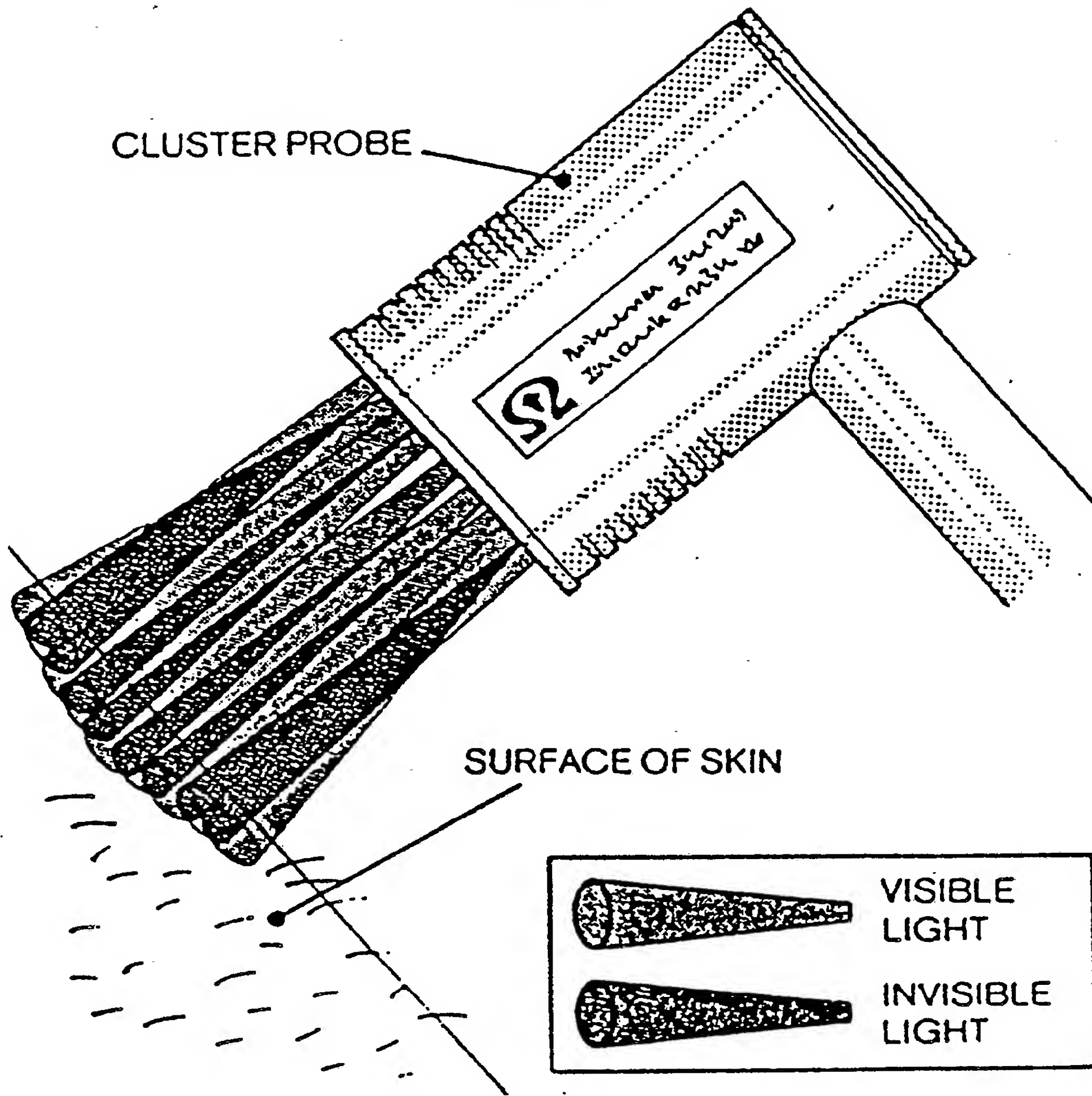


FIG. 3

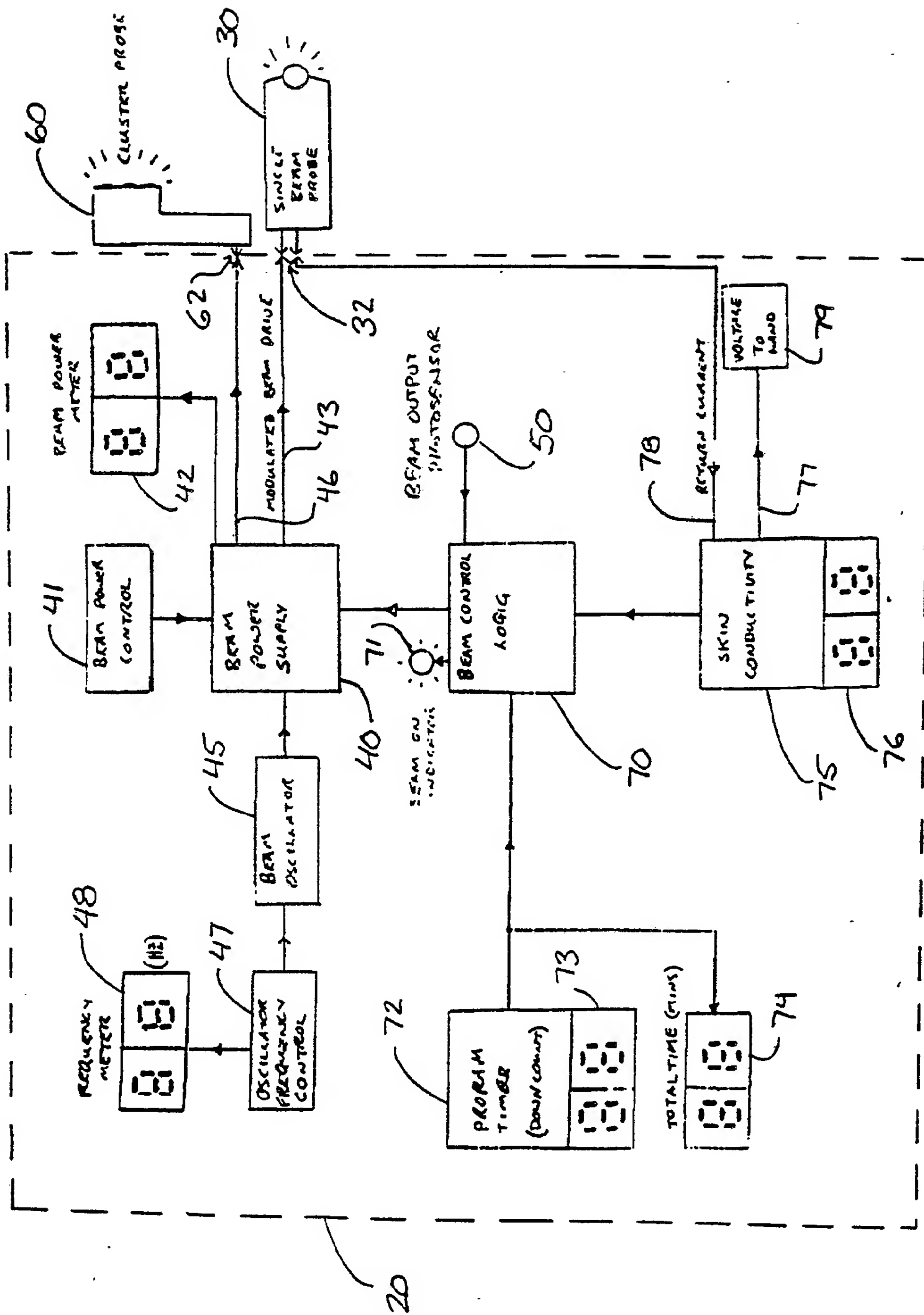


FIG. 4

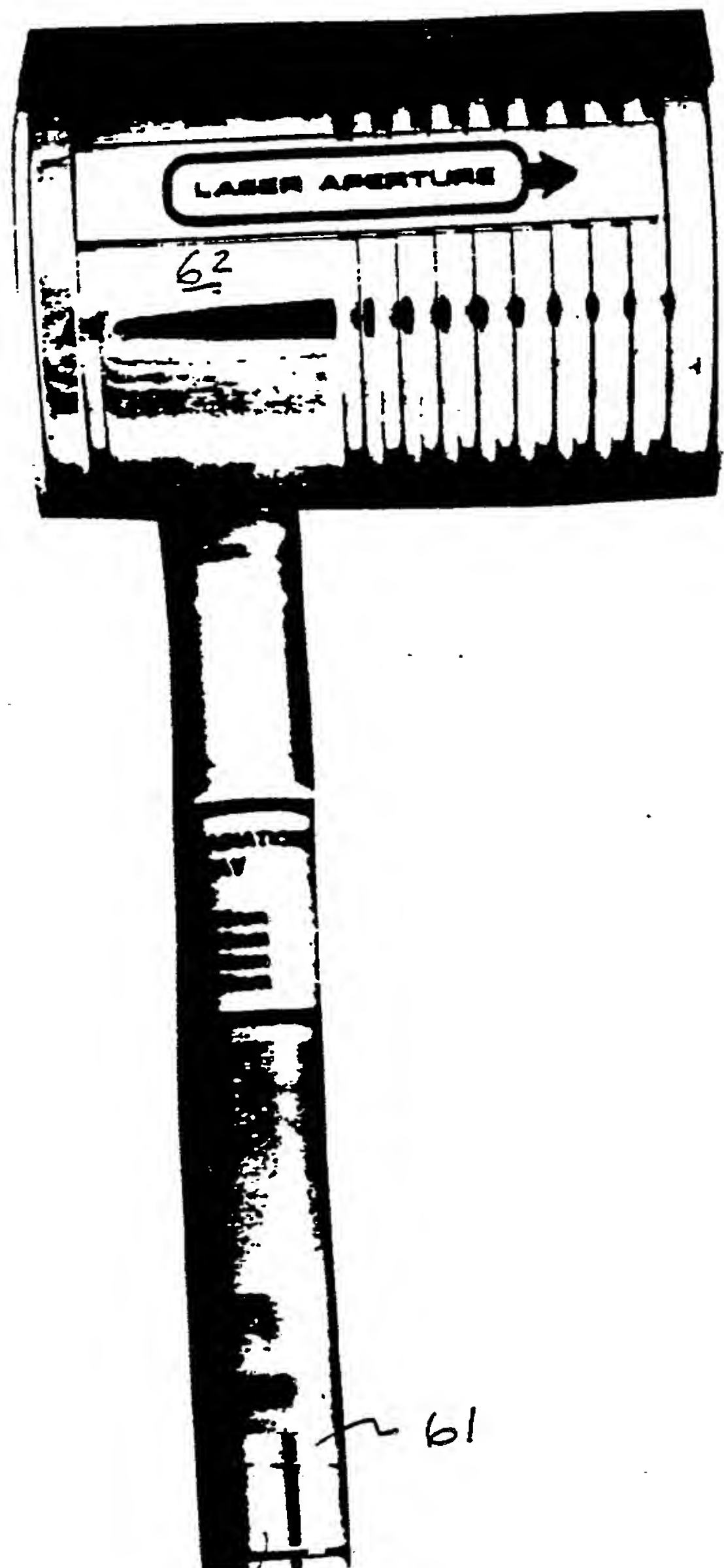


FIG. 5

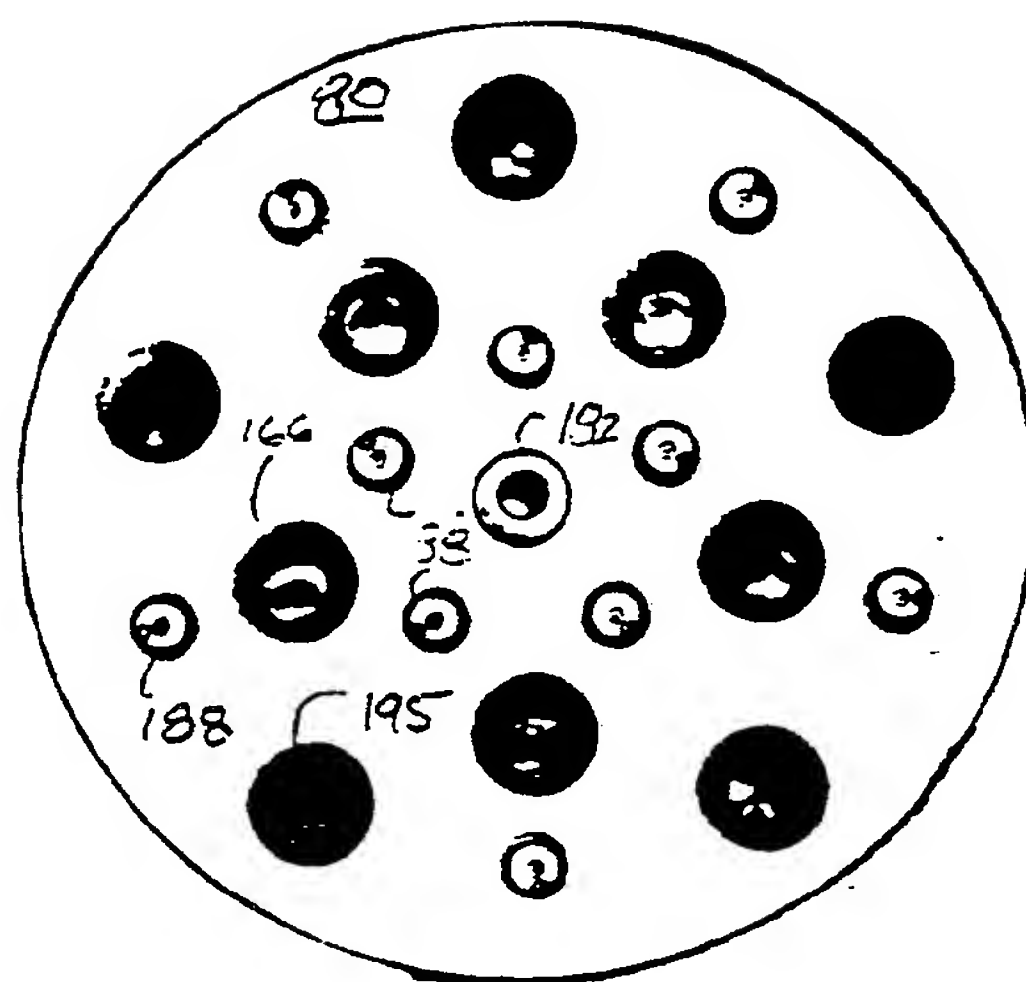


FIG. 6

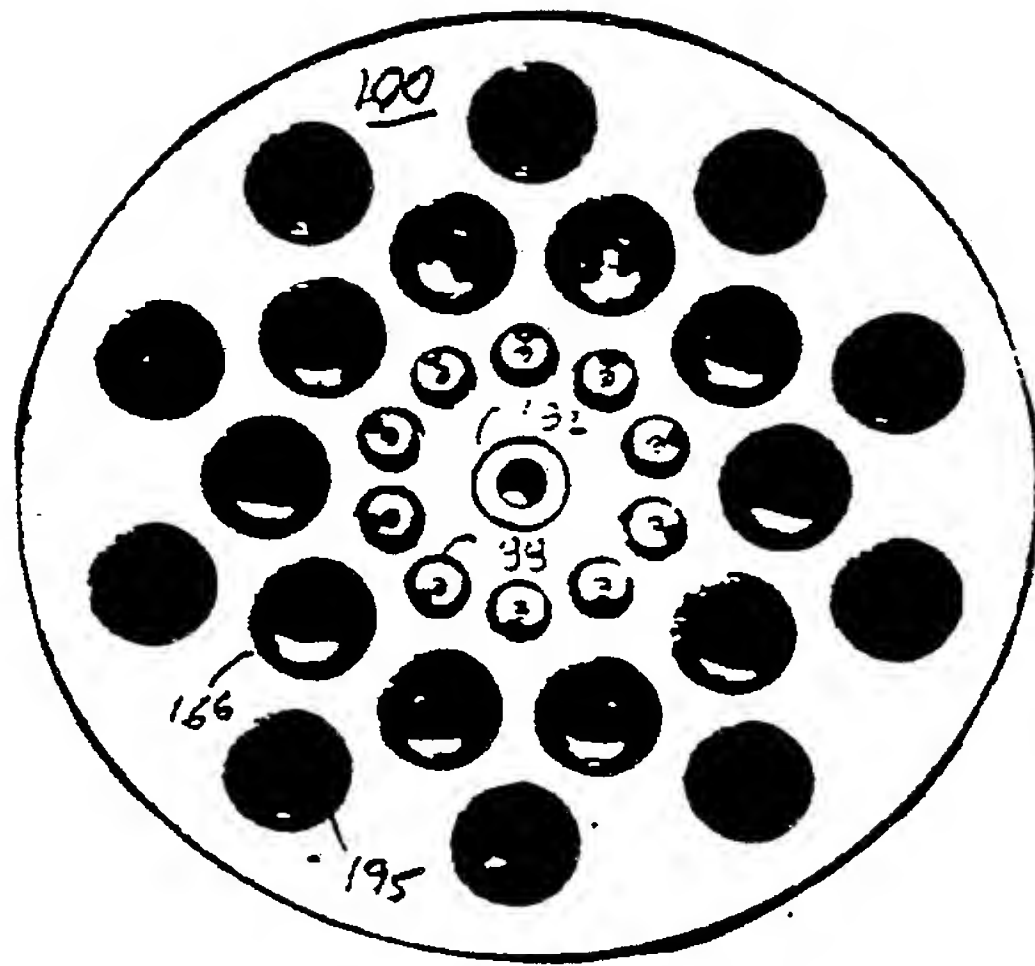


FIG. 8

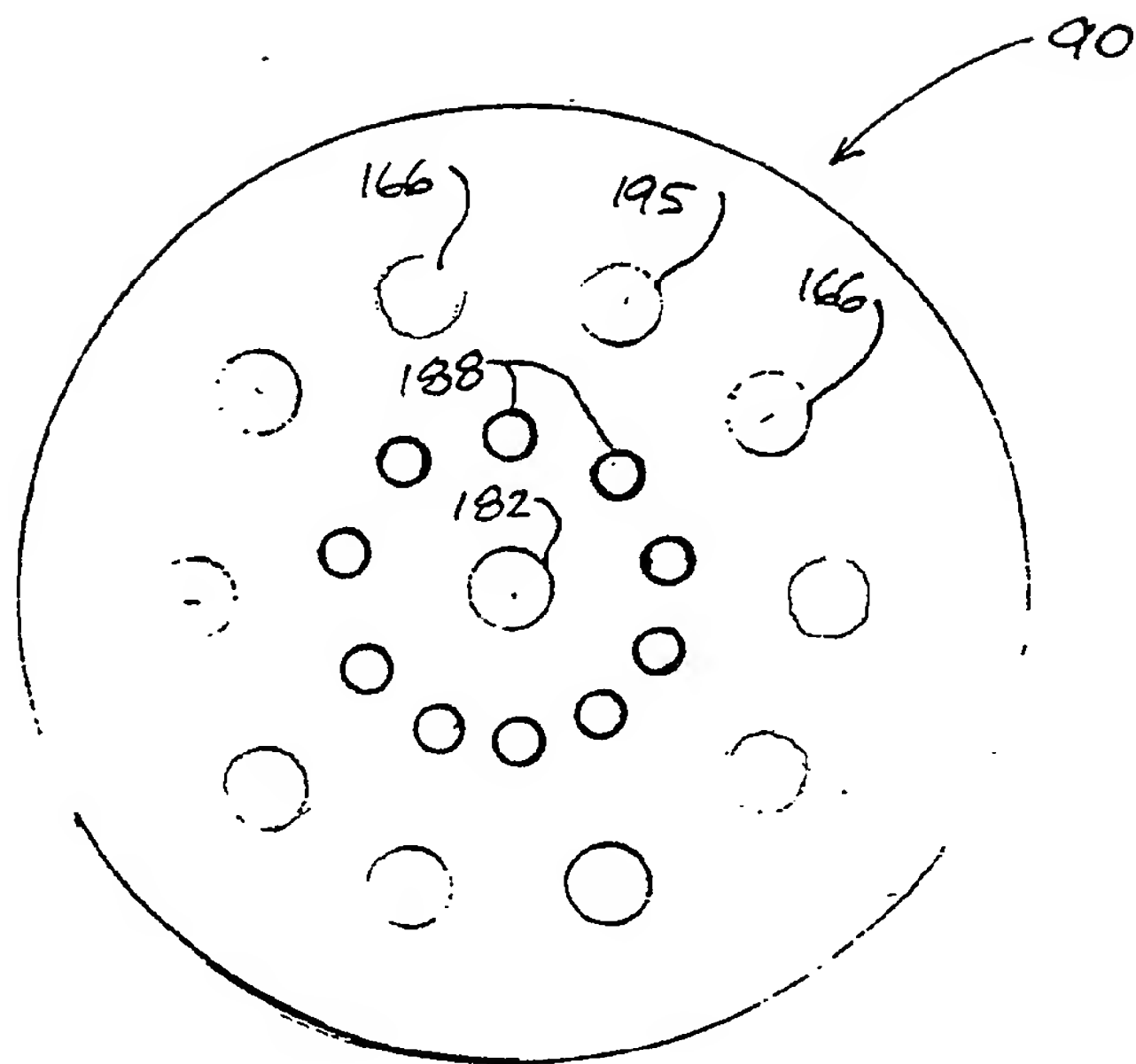


FIG. 7

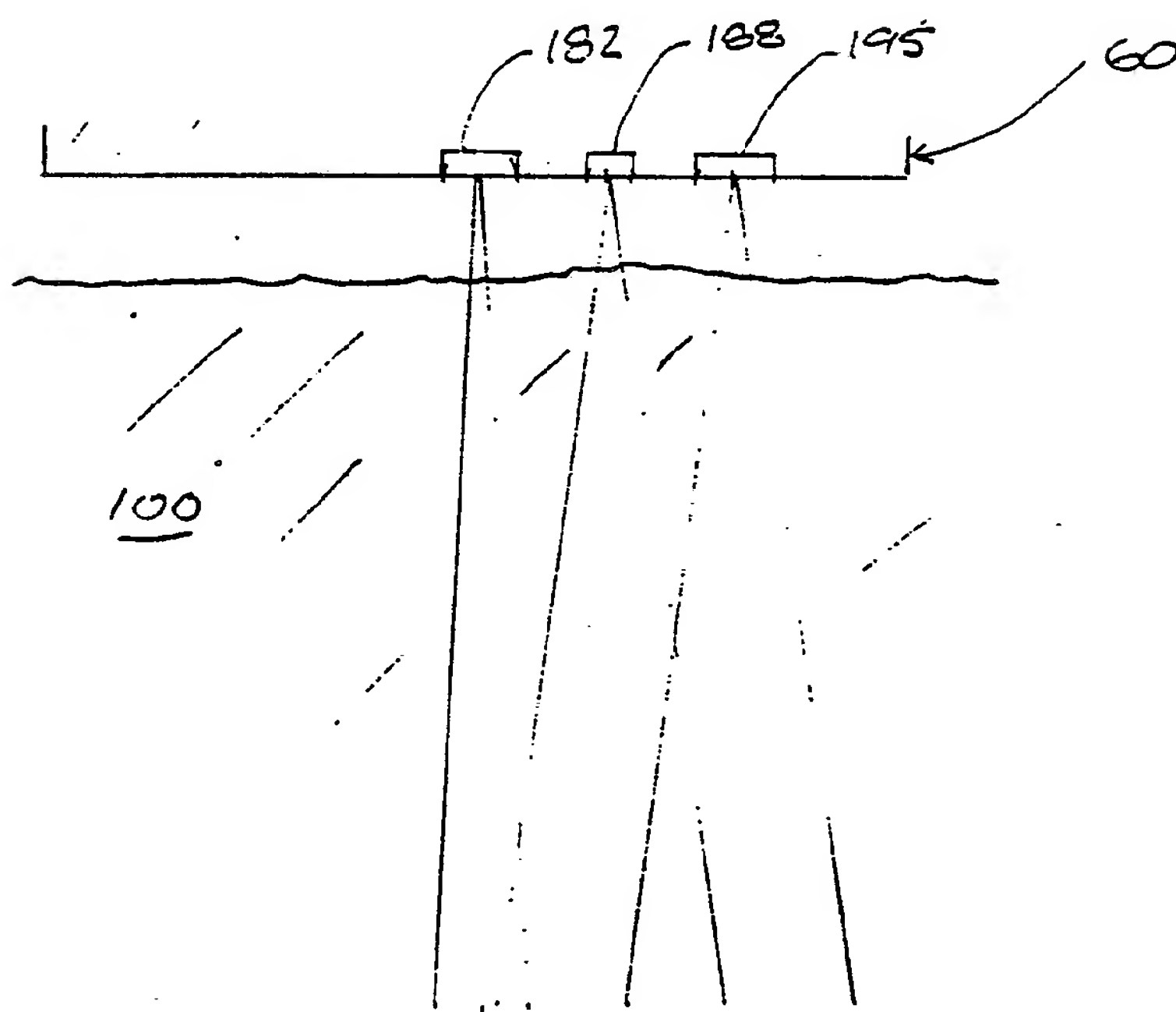


FIG. 9



DOCUMENTS CONSIDERED TO BE RELEVANT			EP 88304792.0
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	CH - A5 - 651 477 (RAUNA) * Totality *	1,10, 13,15- 19,21	A 61 N 5/06
	--		
A	DE - A1 - 3 508 674 (LAMBERTZ) * Claims 7,8,10; page 4, lines 17-19; page 5, lines 19-30; page 6, lines 15-18,29; fig. 1,2 *	1,10, 13,15- 19,21	
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A	FR - A2 - 2 399 256 (SKOVAJSA) * Page 2, line 30 - page 3, line 6; fig. 1-3 *	1,10, 13,15- 19,21	
	--		
A	US - A - 4 646 743 (PARRIS) * Abstract; column 2, lines 42-58; fig. 1,2 *	1,10, 13,15- 19,21	
	--		TECHNICAL FIELDS SEARCHED (Int. Cl.4)
A	DE - U - 7 622 099 (LOHER) * Claims 1-3; page 4, paragraph 4; page 5, last 5 lines *	20	A 61 N A 61 H
	--		
A	EP - A2 - 0 058 105 (JAVELLE) * Abstract; page 6, line 36 - page 7, line 12; fig. 1 *	1,10, 13,15- 19,21	
	--		
A	US - A - 4 535 784 (ROHLICEK) * Abstract; fig. 1-8 *	1	
	--		
The present search report has been drawn up for all claims			
Place of search VIENNA		Date of completion of the search 28-02-1989	Examiner NEGWER
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	



DOCUMENTS CONSIDERED TO BE RELEVANT			EP 88304792.0
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	US - A - 4 112 335 (GONSER) * Column 3, lines 39-59 * --	1	
			TECHNICAL FIELDS SEARCHED (Int. Cl.4)
The present search report has been drawn up for all claims			
Place of search VIENNA		Date of completion of the search 28-02-1989	Examiner NEGWER
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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EUROPEAN PATENT APPLICATION

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54 **Electronic toothbrush.**

57 A tooth-brush comprising a handle (3) and a brush portion (5). The handle contains a piezo-electric generating element (4) having two electrodes (7,8). A diode (9) is situated between electrodes (7,8) for rectifying the flow of negative electrons from the brush portion (5) via the user's body to the handle (3). The flow of electrons induces a reducing process which effectively removes dental plaque.

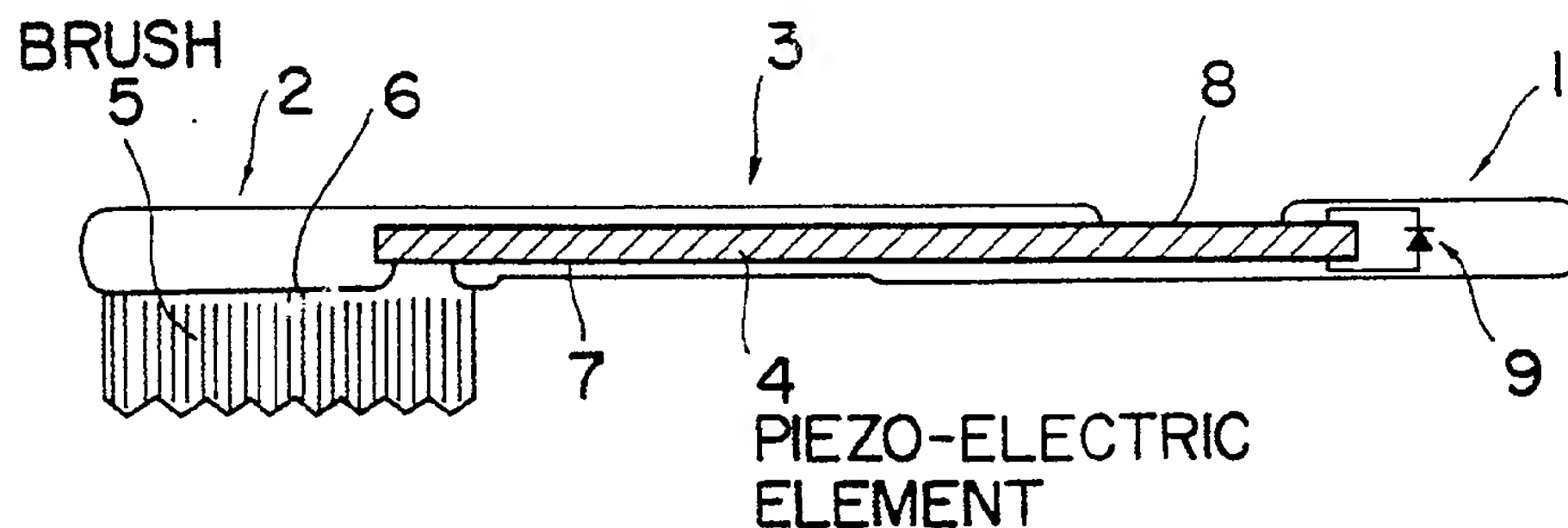


FIG. 1

EP 0 324 120 A1

ELECTRONIC TOOTHBRUSH

BACKGROUND OF THE INVENTION

This invention relates to an electronic toothbrush for a purpose of removing dental plaque by means of brushing and discharging electrons.

A tooth decay is a disease that hard inorganic teeth are decayed by an acid produced by bacteria in a mouth. Dental plaque, that is composed of propagating bacteria, depositing protein and inorganic compound in saliva, overspreads and builds up on a tooth-surface. Tartar is produced by calcification of the plaque which main ingredient is calcium phosphate. Pyorrhea alveolaris is an inflammation of gums caused by plaque left on a root of tooth and under a gum line.

A conventional electronic toothbrush using a dry battery or solar battery generated electrons that decompose plaque and the neutralize lactic acid by means of a reducing process around teeth. This reducing process is caused of the electrons that flow through conductive saliva and water with positive and negative ions, for example, kalium, sodium, magnesium, bicarbonate, chlorine, phosphoric acid, etc. However, the conventional electronic toothbrush is generally high in price because of using a complicated waterproof structure and an expensive battery. Furthermore, there are other drawbacks that a life of a dry battery is limited and an output voltage of a solar battery is low.

SUMMARY OF THE INVENTION

It is an object of the present invention, therefore, to simplify a structure of an electronic toothbrush, to reduce a cost without using a high price battery, to obtain a high output voltage and to get unlimited life. These objects of the present invention are realized by utilizing a piezo-electric element mounted in a handle of a toothbrush.

Electrodes are formed on both sides of said piezo-electric element located in the center portion of the handle, and then the electrode on one side is exposed in close vicinity to the brushing portion and the electrode on the other side is exposed on the gripped portion of the handle. On the occasion of toothbrushing, positive and negative charges are generated on both sides of the piezo-electric element as a result of bending and vibration of the handle.

It is necessary to select proper polarity of the piezo-electric element and put in a diode between both electrodes for generating selectively negative

charges on the electrode exposed in close vicinity to the brushing portion. Electrons flow from the electrode near the brushing portion to the electrode on the gripped portion of the handle, through saliva and water in a mouth, teeth, a root of tooth, a human body and a hand. Consequently, dental plaques are removed effectively by a reducing process due to the electrons around teeth.

According to one aspect of this invention, for achieving the objects described above, there is provided an electronic toothbrush comprising: a piezo-electric element with piezo-electric characteristic mounted in a handle between a gripped portion and a brushing portion of said electronic toothbrush; an exposed electrode in close vicinity to said brushing portion and an opposite exposed electrode on said gripped portion of said handle formed on both sides of said piezo-electric element, respectively.

The nature, principle and utility of the invention will become more apparent from the following detailed description when read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is described in greater detail with reference to the drawings, in which:

FIG.1 is a cross sectional view of a basic embodiment of the present invention;

FIG.2 is illustrative of a principle of a piezo-electric element used in the present invention;

FIGs.3 and 4 are characteristic curves observed in an oscilloscope of output voltages generated by piezo-electric elements without and with a diode, respectively;

FIGs.5 and 6 are perspective views illustrative of piezo-electric bimorphs;

FIGs.7 and 8 are cross sectional views illustrative of location of piezo-electric elements in handles;

FIG.9 is a cross sectional view illustrative of a reformed embodiment of the present invention; and

FIG.10 is a perspective view illustrative of another embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The basic embodiment of the present invention is shown in the cross sectional view of FIG.1. A piezo-electric element 4 with piezo-electric characteristic is operatively mounted in a handle 3 of a toothbrush between a gripped portion 1 and a brushing portion 2 of the handle 3. A diode 9 with rectifying action is used to electrically connect an electrode 7 and an electrode 8 formed on both sides of the piezo-electric element 4. The electrode 7 is exposed in close vicinity to the brushing portion 2 on the brush 5 side of the handle 3, and the electrode 8 is exposed on the opposite side. The brush 5 is laid on the surface 6 of the brushing portion 2.

FIG.2 illustrates the principle of generating the output voltage in the piezo-electric element 10. When the piezo-electric element 10 is expanded and contracted horizontally, positive and negative charges are generated on the electrodes 11 and 12, respectively. The piezo-electric element 10, for example a polyvinylidene fluoride film, consists of countless dipoles that allow the element to create electric charges resulting from expansion and contraction applied to the element. If both electrodes 11 and 12 are electrically connected, the electric current flows from the electrode with negative charges to the electrode with positive charges.

FIGs.3 and 4 illustrate the characteristic curves of the output voltage generated from the piezo-electric element, as shown in FIG.2, mounted on a piece of plastic plate as a cantilever at the time of tapping without and with the diode 9, respectively. The ordinate axis denotes the voltage V by 2 volt per one scale and the abscissas axis the time t by 20 msec per one scale, respectively. In the characteristic curve of FIG.3, without the diode 9, the output voltage is lower and the output voltage of opposite polarity is generated at the time of resilience of the plastic plate with the piezo-electric element. In FIG.4, with the diode 9, the output voltage is higher and nearly rectified without opposite polarity.

The present invention utilizes the phenomenon mentioned above. When the handle 3 of the toothbrush shown in FIG.1 is bent, the output voltage is generated according to expansion and contraction of the piezo-electric element 4. In other words, the output voltage results in between the brush 5 side electrode 7 exposed in close vicinity to the brushing portion 2 and the other electrode 8 exposed on the gripped portion 1 of the handle 3. The external force is always applied to the brush 5 when toothbrushing, and therefore the handle 3 of the toothbrush is bent almost always toward the surface 6 with the brush 5. The piezo-electric element 4 is polarized so that the negative charges are generated on the electrode 7 due to the expansion and the contraction corresponding to the bending of the

handle 3. Electrons flow in the circuit from the electrode 7 with negative charges to the electrode 8 with positive charges, through conductive saliva and water in a mouth, teeth or gums, a human body and a hand. Furthermore, to generate the electrons only out from the electrode 7 and to obtain a higher output voltage, the diode 9 rectifying action is electrically connected between the electrodes 7 and 8. On the occasion that positive and negative charges are generated on the electrodes 7 and 8, respectively, most of the electric current flows in the diode 9 with low resistivity due to the forward direction, not in the circuit of the mouth and the human body with relatively high resistivity. Then, the electric current from the electrode 7 to the electrode 8 is rectified as shown in FIG.4, the higher negative output voltages is generated only on the electrode 7. In general, the diode used in the present invention is low priced due to the small size and has water-resisting quality compared with a dry battery. Moreover, the piezo-electric element, a polyvinylidene fluoride film, for example, is low priced and water-resistant.

The other embodiments of the present invention are illustrated in FIGs.5-10.

The bending motion of the plastic handle 3 between the gripped portion 1 and the brushing portion 2 is mentioned above in FIG.1. The negative charges corresponding to the bending of the handle 3 must be generated on the electrode 7. As mentioned in the summary of the invention, it is necessary to obtain electrons near the brushing portion 2 for the purpose of effective removing plaque and tartar by brushing and a reducing process. The piezo-electric bimorph 13, the laminate of the piezo-electric elements as shown in FIG.5, generated different charges on the electrodes 14 and 15 in response to the bending.

Another piezo-electric bimorph in FIG.6, the laminate of a piezo-electric element 17 and a metal sheet 16, can be used in the present invention. In this case, different charges are generated on electrode 18 and the metal sheet 16 due to the bending. The piezo-electric element 17, a polyvinylidene fluoride film, is relatively flexible, but the metal sheet 16 is rigid and has not flexibility of expansion and contraction. On the occasion that the piezo-electric element 17 of the bimorph in FIG.6 is located on the brush side of the handle of the toothbrush, the piezo-electric element 17 is mainly expanded. In the contrary case, the piezo-electric element 17 is mostly contracted when toothbrushing. The piezo-electric elements of the bimorphs shown in FIGs.5 and 6 are necessary to be polarized so that the negative charges are generated on the electrodes near the brushing portion. Subsequently, the other embodiments shown in FIGs.7 and 8 which can achieve effectively the object of the

present invention use the single layer piezo-electric elements 4, not bimorphs. These single layer elements 4 that are mounted in the location shifted from the center line X-X of the handle 3 are consequently contracted and expanded as shown in FIGs.7 and 8, respectively, when bending of the handle 3. The polarizing directions of the piezo-electric elements 4 are perpendicular to the elements 4, and opposite directions, in FIGs.7 and 8, respectively. As noted above, the object of the present invention is achieved according to locating the piezo-electric elements 4 which are expanded and contracted due to the bending of the handle 3. It is a matter of course that the diodes 9 with rectifying action are electrically connected with both opposite electrodes to gain effectively the higher output voltage.

In the embodiment of the present invention, as shown in FIG.9, the only electrode 7 formed on one side of the piezo-electric element 4 is exposed in close vicinity to the surface 6 of the brushing portion, and the only electrode 8 is exposed on the gripped portion 1, respectively. Moreover, the part of the piezo-electric element 4 with electrodes on both sides is sealed hermetically in the plastic of the handle, hence the short circuit between electrodes 7 and 8 is not caused when toothbrushing.

The more practical embodiment of the present invention is illustrated in FIG.10. A metal plate 19 is connected directly and operatively with the electrode 8 exposed on the gripped portion 1 of the handle 3 and fastened around the gripped portion 1. Furthermore, the diode 9 mounted in the gripped portion 1 is electrically connected between the electrode 7 and the metal plate 19. When toothbrushing, a hand touches almost always the metal plate 19, and therefore the object of the present invention is effectively achieved.

It should be understood that many modifications and adaptations of the invention will become apparent to those skilled in the art and it is intended to encompass such obvious modifications and changes in the scope of the claims appended hereto.

Claims

1. An electronic toothbrush comprising: a piezo-electric element with piezo-electric characteristic mounted in a handle between a gripped portion and a brushing portion of said electronic toothbrush; an exposed electrode in close vicinity to said brushing portion and an opposite exposed electrode on said gripped portion of said handle formed on both sides of said piezo-electric element, respectively.

2. An electronic toothbrush as claimed in Claim 1 further includes a diode with rectifying action electrically connected with said electrodes formed on both sides of said piezo-electric element.

3. An electronic toothbrush as claimed in Claim 1 or 2 wherein said piezo-electric element is a thin and flexible piezo-electric material.

4. An electronic toothbrush as claimed in any of claims 1 to 3 wherein said piezo-electric element is a bimorph structure.

5. An electronic toothbrush as claimed in any claims 1 to 4 wherein thick-nesses in compartments of plastic for covering said piezo-electric element are different at an upper portion and a lower portion of said piezo-electric element.

6. An electronic toothbrush as claimed in any of claims 1 to 5 which has an electrode only on one side of said piezo-electric element at an exposed area in close vicinity to said brushing portion of said handle.

7. An electronic toothbrush as claimed in any of claims 1 to 6 which has a metal plate electrically connected with a top of said electrode and a diode, said diode being electrically connected with said another electrode formed on said piezo-electric element, said metal plate being fastened around said gripped portion of said handle.

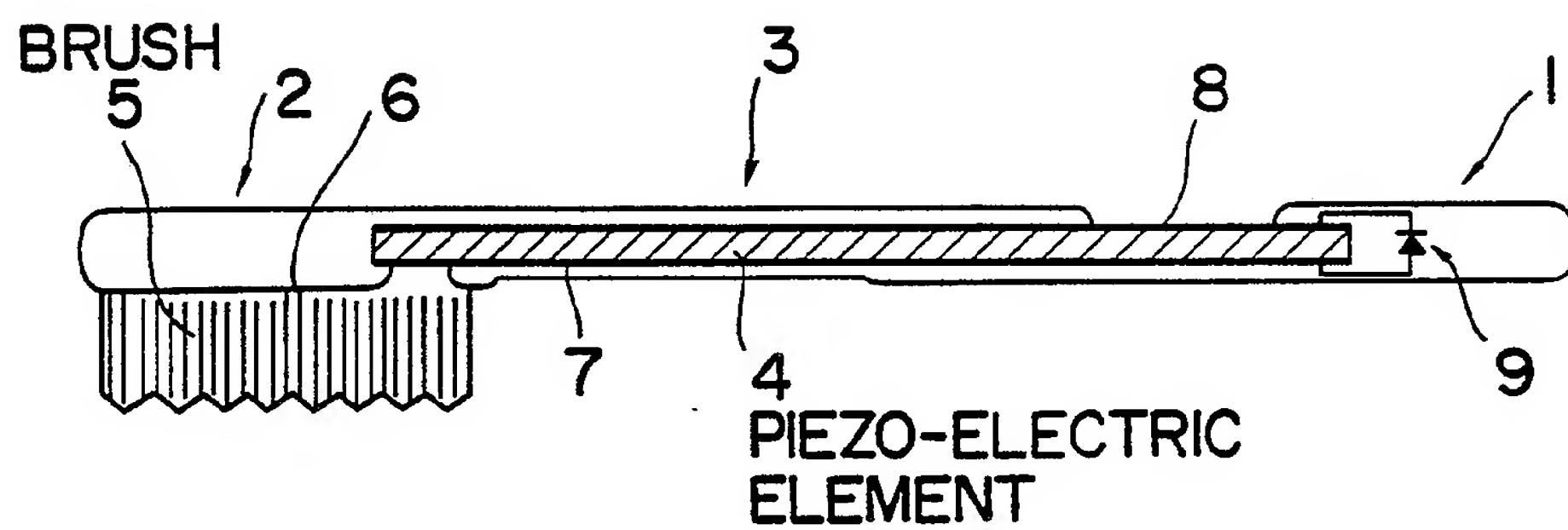


FIG. 1

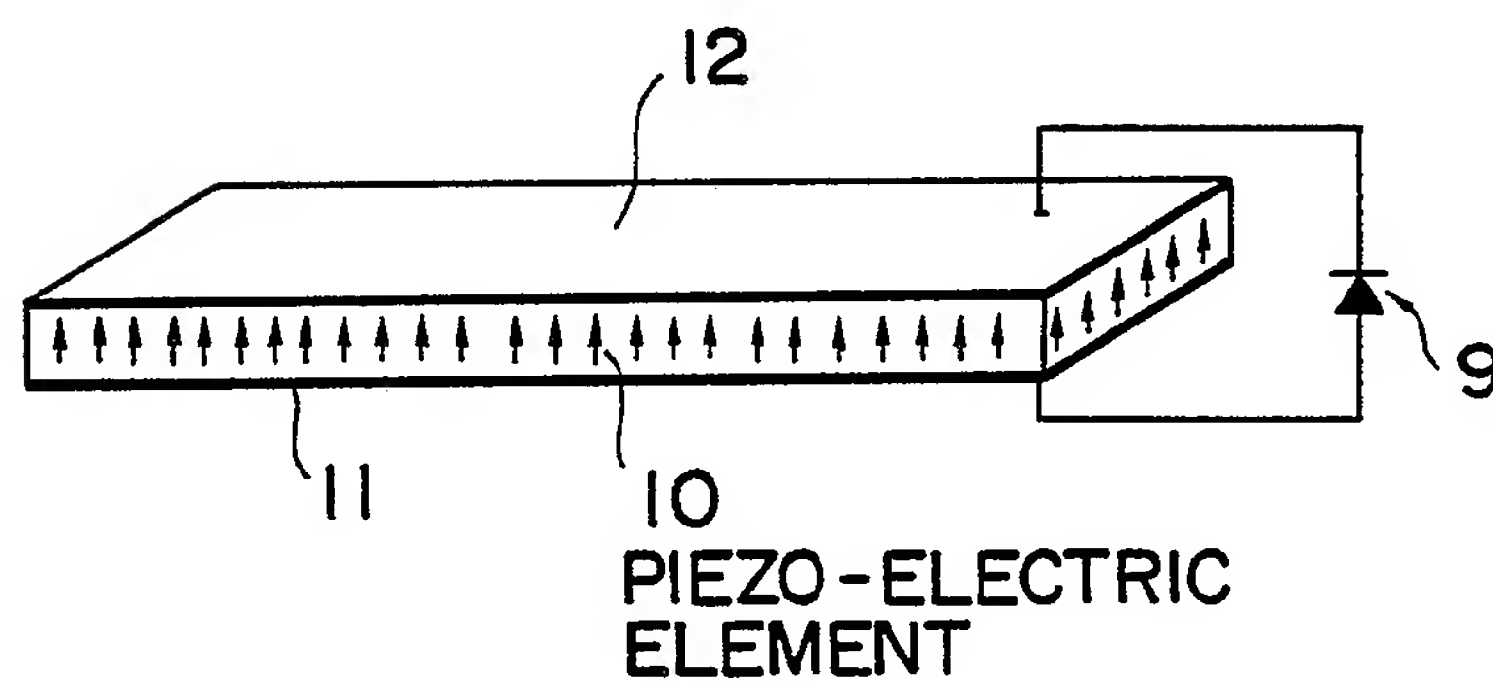


FIG. 2

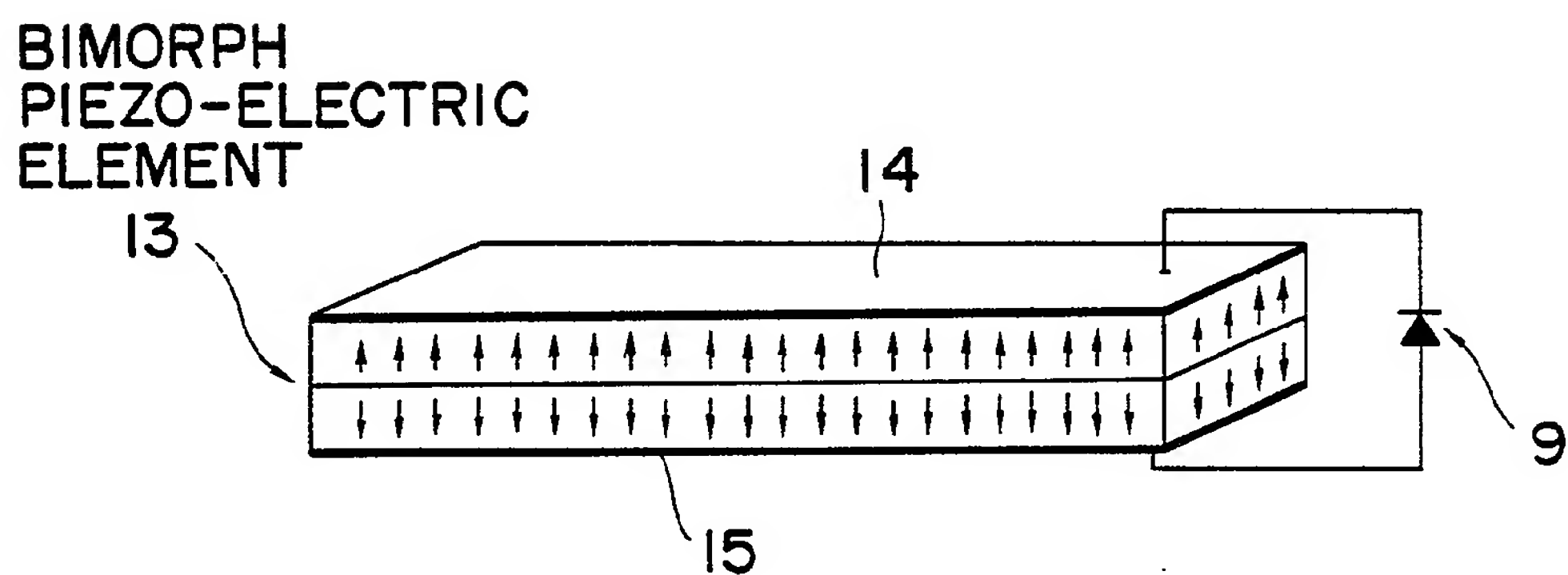


FIG. 5

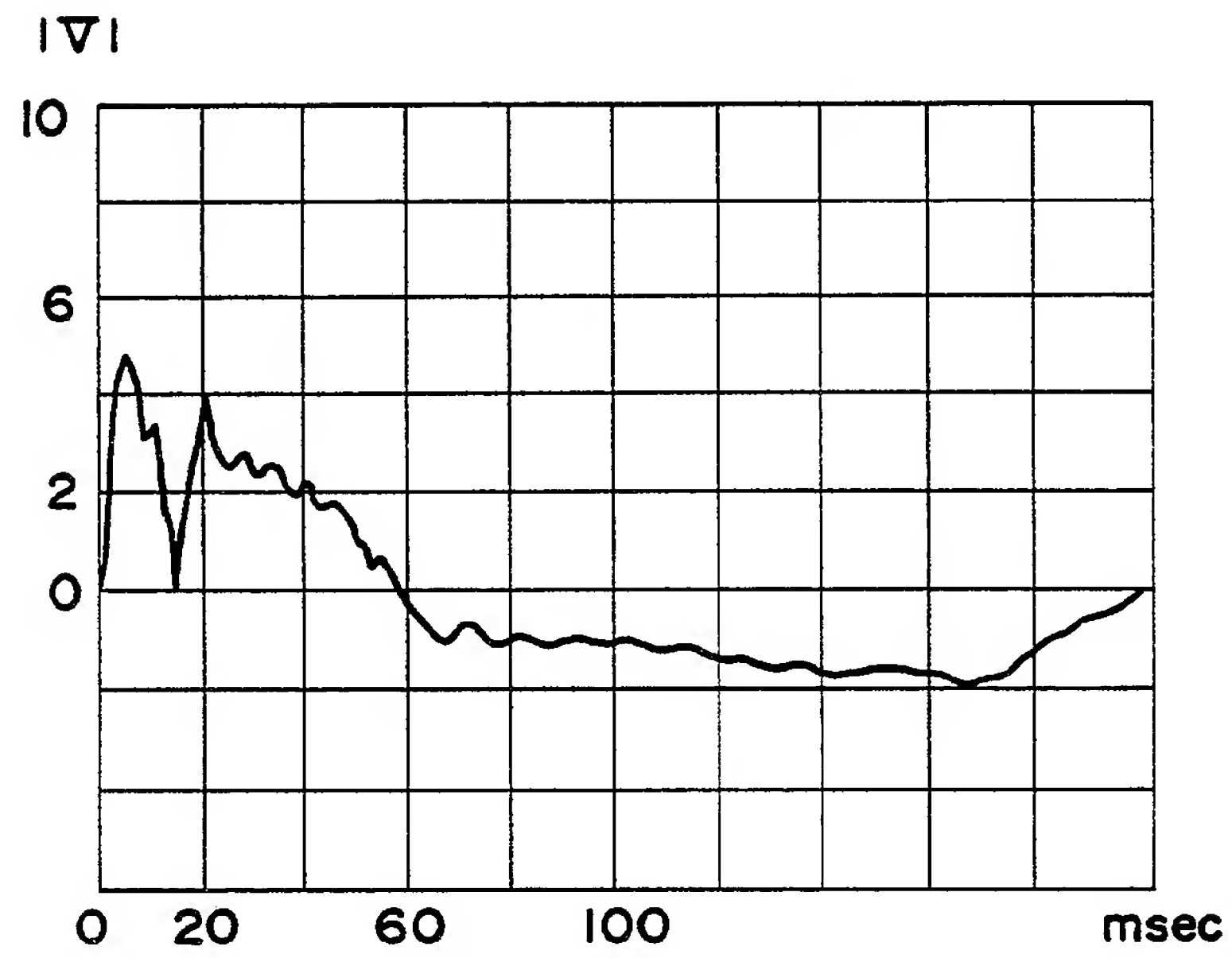


FIG. 3

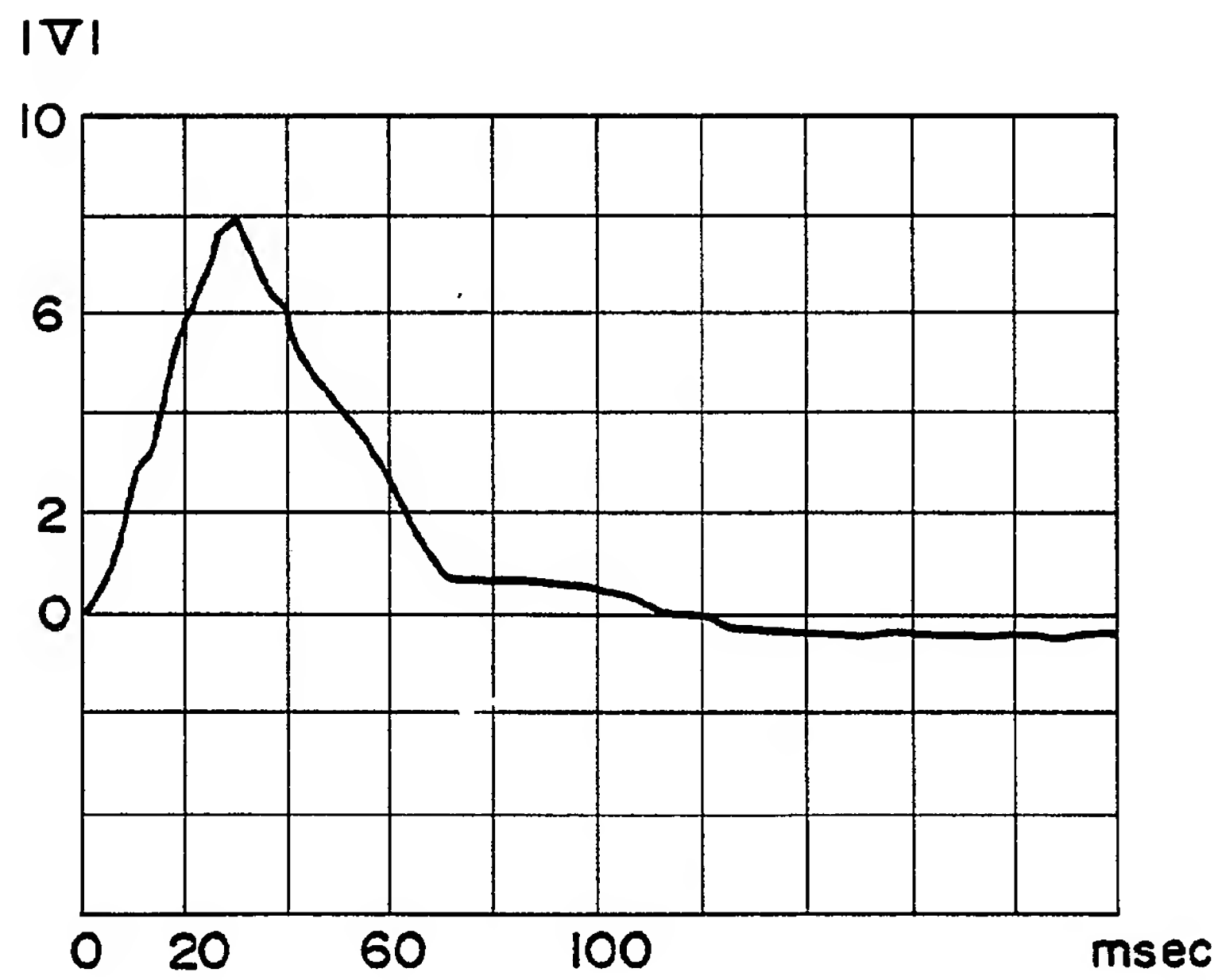


FIG. 4

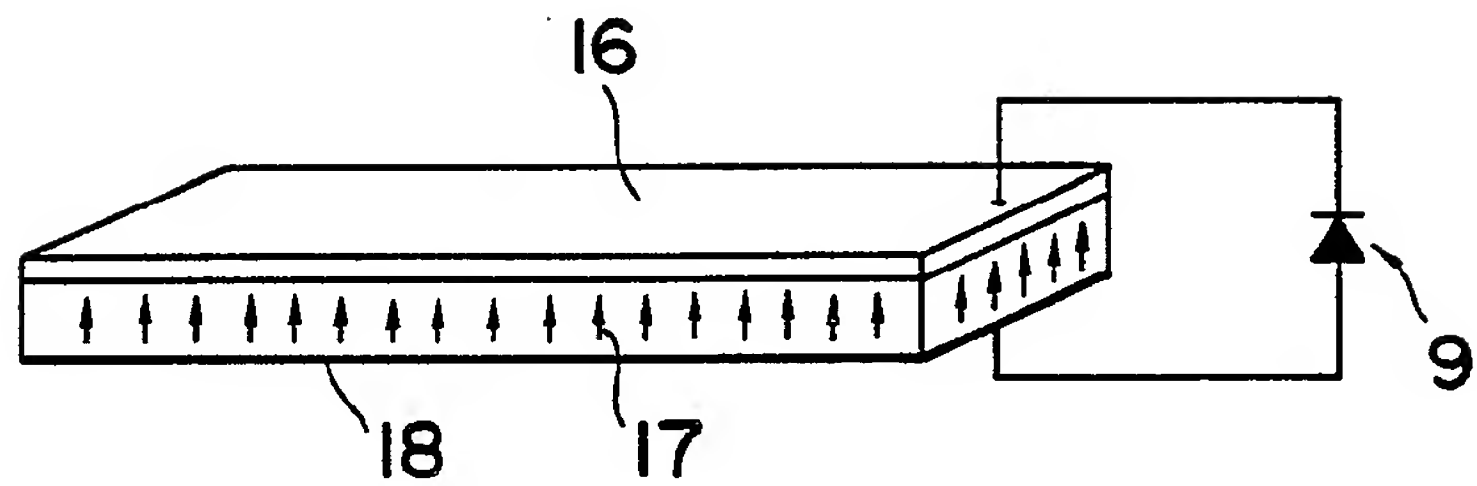


FIG. 6

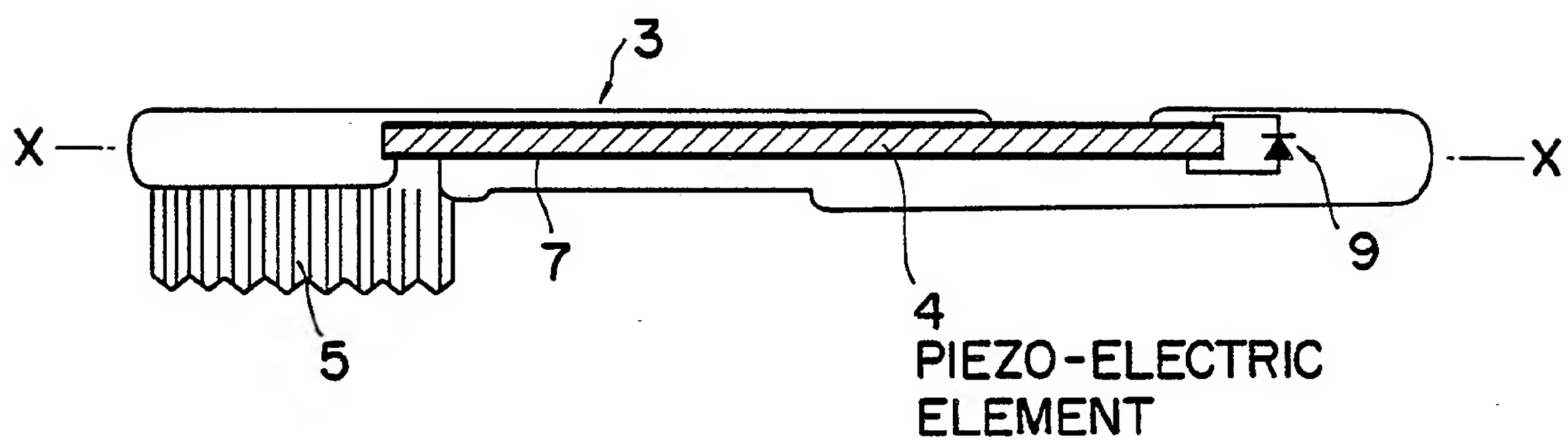


FIG. 7

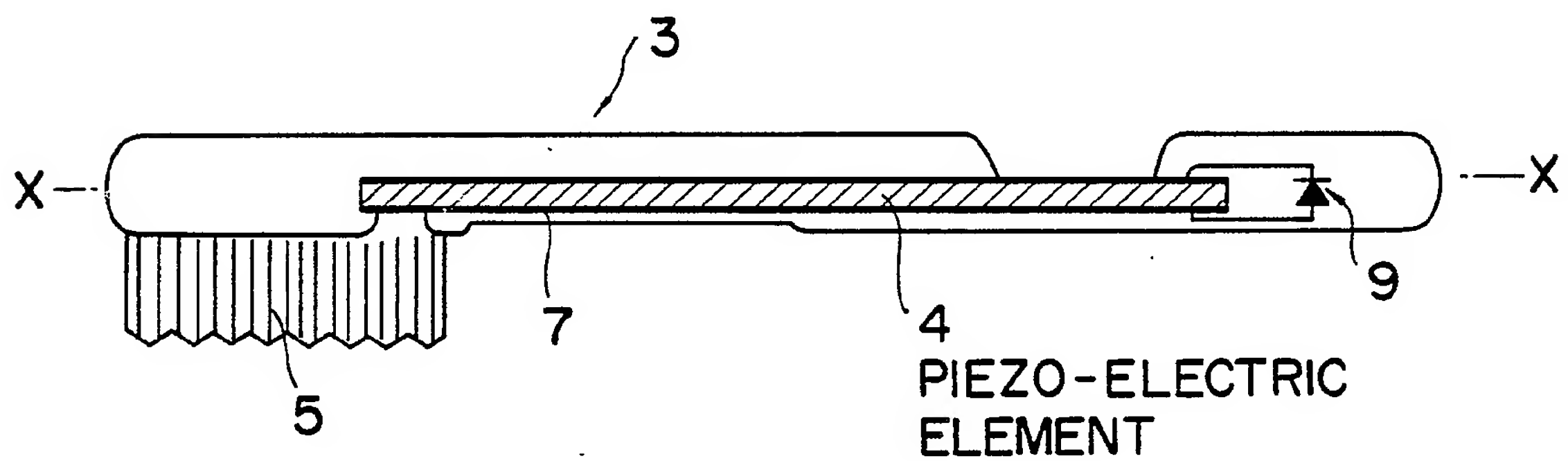


FIG. 8

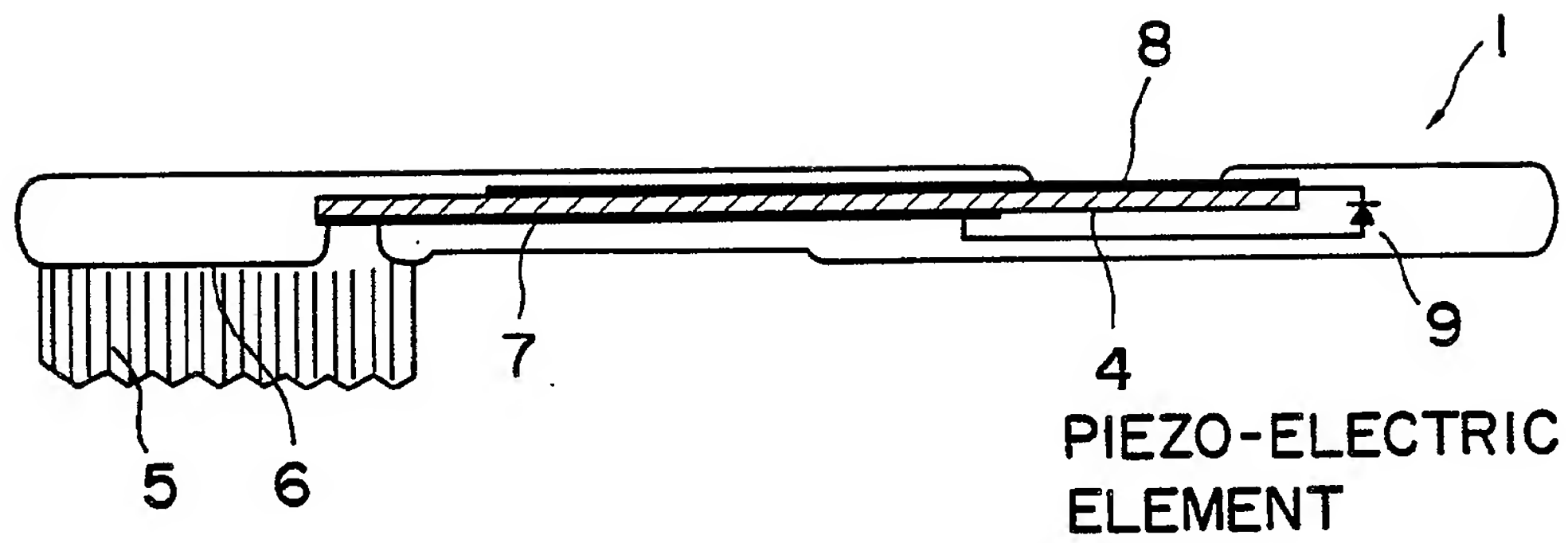


FIG. 9

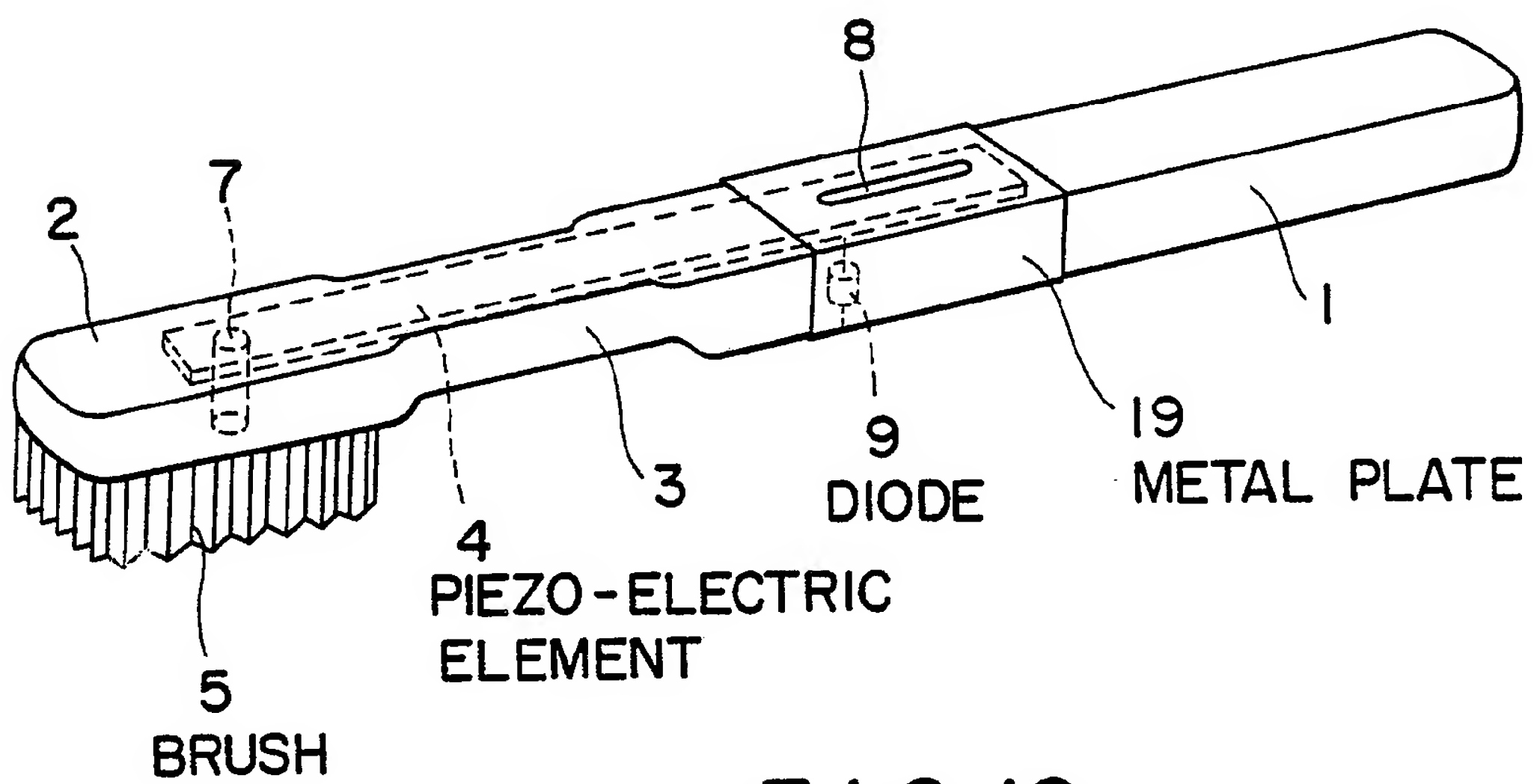


FIG. 10



DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	CH-A- 466 215 (SIMOR) * Claim; figures 1-12 * ---	1	A 46 B 15/00
A	FR-A-1 583 683 (CHEMWAY CORP.) * Claim; figure * ---	1	
A	EP-A-0 199 158 (BAUER) * Page 5, lines 116-130 * -----	1	
			TECHNICAL FIELDS SEARCHED (Int. Cl.4)
			A 46 B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 12-04-1989	Examiner ERNST R.T.
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

Device for applying light.

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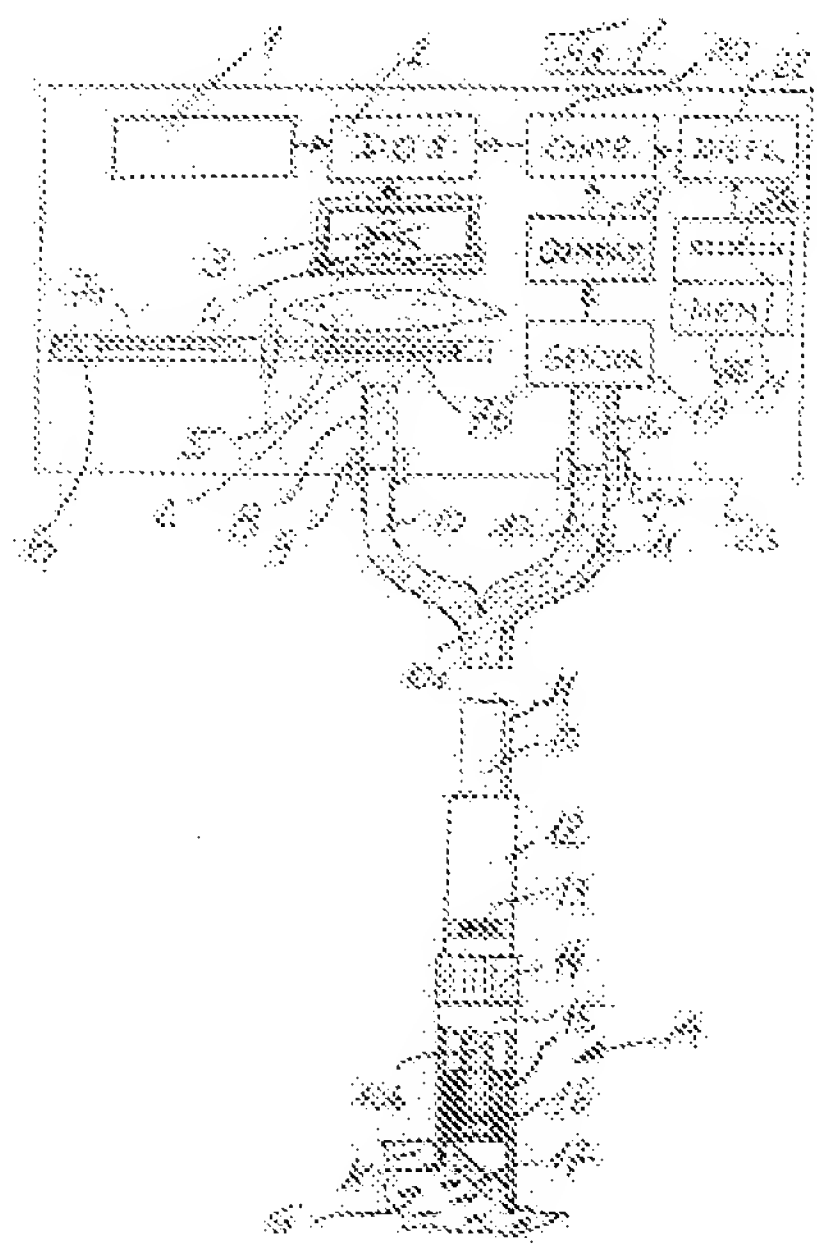
DE3012150 (A1)

EP0462302 (A1)

EP0406454 (A1)

Abstract of **EP 0563953 (A2)**

For the purpose of exactly metering light quantities incident from a light source (3) via an optical light guide (10) and an applicator (A) and a contact surface (K) onto an object (G), that proportion of the application light (L) which is not transmitted to the object is guided back by an optical light guide to a sensor (18) which records this proportion of light in order to influence a control device (20) and/or a metering device (2) for the light source.





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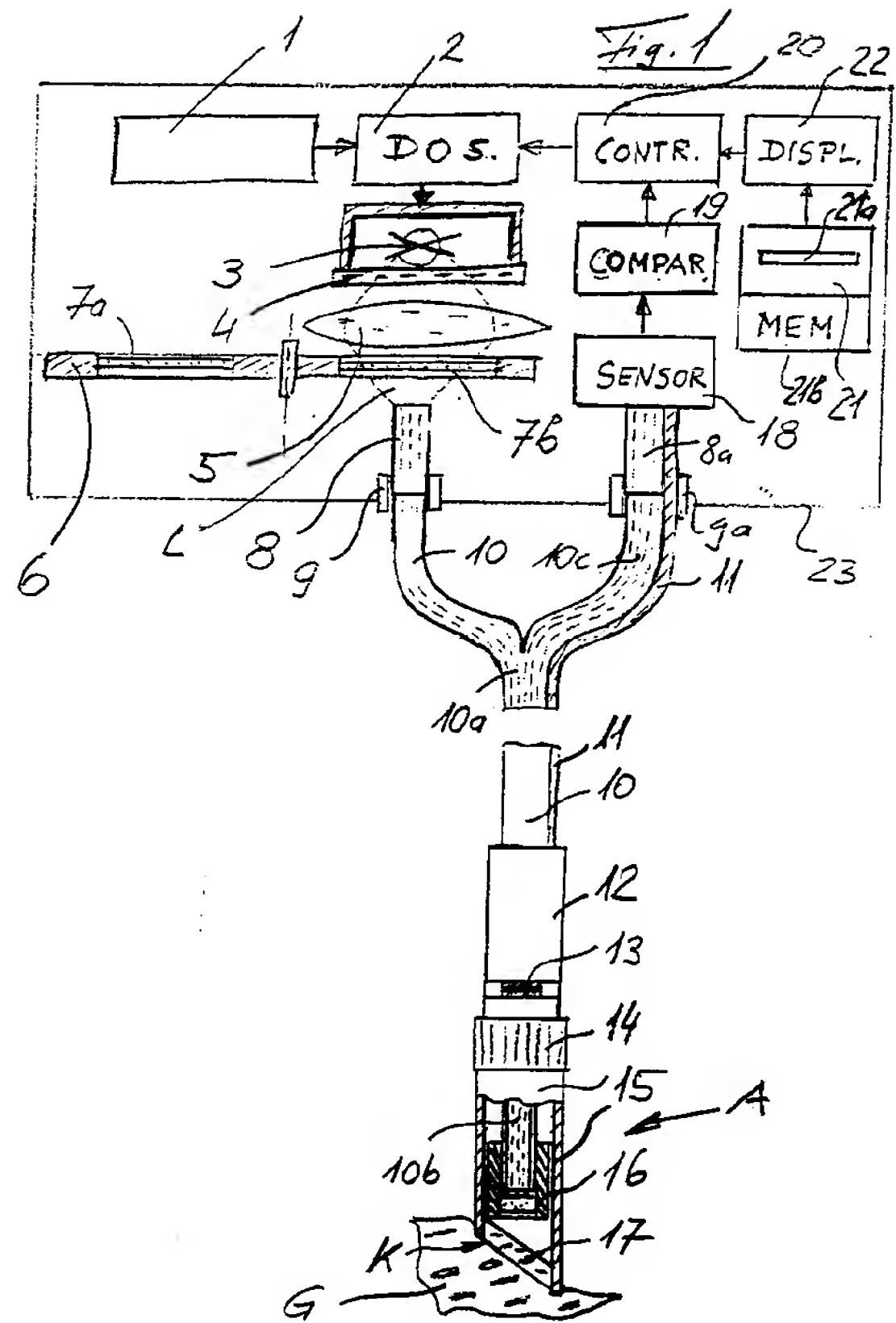
54

Vorrichtung zum Applizieren mit Licht.

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Zum genauen Dosieren von Lichtmengen, die von einer Lichtquelle (3) über einen Lichtleiter (10) und einen Applikator (A) und eine Kontaktfläche (K) auf einen Gegenstand (G) einfallen, wird der nicht auf den Gegenstand übertragene Anteil des Applika-

tionslichts (L) über einen Lichtleiter zu einem Sensor (18) zurückgeleitet, der diesen Lichtanteil zum Beeinflussen einer Steuereinrichtung (20) und/oder einer Dosiereinrichtung (2) für die Lichtquelle erfaßt.



Die Erfindung bezieht sich auf eine Vorrichtung der im Oberbegriff des Anspruchs 1 genannten Gattung.

Eine derartige Vorrichtung ist bereits bekannt (US-A-4718 417, DE-C-2829 516 und DE-A-3319 203). Hierdurch soll Primärlicht zu einer Photokoagulation in Gewebe oder dergleichen führen und wird mit anderer Wellenlänge vom Gegenstand emittierte und dem Koagulationsgrad entsprechende thermische Strahlung als Sekundärlicht vom Sensor ermittelt, der gut gegen Primärlicht abgeschirmt wird.

Ferner ist es bekannt, polarisiertes Licht, insbesondere LASER-Licht, auf Zellen und Gewebe zu applizieren, wodurch beispielsweise Wachstumsfaktoren stimuliert werden. Auch langwellige Wärmestrahlen, kurzwellige UV-Strahlen und nicht kohärente linear polarisierte Lichtstrahlen werden zum Applizieren von organischen Substanzen, beispielsweise lebendem Gewebe, verwendet, um beispielsweise die Wundheilung zu fördern oder Muskelverspannungen zu lösen oder oberflächliche Bräunungseffekte zu erzielen. Die Dosierung solcher Laserstrahlen, UV-Strahlen und dergl. ist jedoch nicht einfach zu bewerkstelligen, wenn sich die zu applizierende Lichtenergiemenge nur in einem beschränkten Toleranzbereich befinden darf, um unerwünschte Beschädigungen des applizierten Gegenstandes, beispielsweise Beschädigung von Hautgeweben, zu vermeiden.

Der Erfindung liegt daher die Aufgabe zugrunde, eine Vorrichtung der eingangs genannten Gattung mit einfachen Mitteln dahingehend zu verbessern, daß eine genaue Dosierung möglichst automatisch erfolgen kann. Darüber hinaus ist erwünscht, den Energiebedarf insgesamt gering zu halten.

Die Erfindung ist im Anspruch 1 gekennzeichnet und weitere Ausbildungen derselben sind in Unteransprüchen beansprucht und werden in der folgenden Beschreibung auch anhand der Zeichnung näher erläutert.

Bei der Erfindung wird ein insbesondere aus Glas- oder Kunststoffasern bestehender Lichtleiter dazu verwendet, das Licht auf möglichst der gesamten Strecke zwischen der Lichtquelle und dem Applikator zu leiten und "Luftübergänge" weitgehend zu vermeiden. Dieser weist eine Kontaktfläche auf, welche einerseits den Lichtübergang zum zu bestrahlenden Gegenstand gewährleistet, andererseits in Verbindung mit der an die Kontaktfläche angelegten Oberfläche des Gegenstands aber auch eine "Reflexionsfläche" bildet, welche nicht auf den Gegenstand übertragenes Primärlicht bzw. Applikationslicht durch Reflexion, Streuung, Beugung oder dergl. wieder aufnimmt und über insbesondere den gleichen Lichtleiter, der schon zum Hinführen des Lichts zur Kontaktfläche diente, zu einem Sensor

zu leiten, welcher dieses zurückgeleitete Primärlicht erfaßt. Dies ist unterschiedlich zu dem im DE-U-90 17 070 gemachten Vorschlag, einen Teil des vom Sensor zum Lichtleiterende geleiteten Lichts auszublenden und zum Steuern der Lichtquelle zu verwenden. Das Ausgangssignal des Sensors gelangt bei der Erfindung zu einem Komparator, welcher als Vergleichseinrichtung dieses vom Sensor erfaßte Licht bzw. eines davon abgeleiteten Signalwerts mit einem Vergleichswert vergleicht. Das Vergleichsergebnis dieses Vergleichs im Komparator dient als Steuergröße für eine Steuereinrichtung, welche die Dosiereinrichtung zum richtigen Dosieren der von der Lichtquelle abzugebenden Lichtenergiemenge steuert. Die Steuereinrichtung kann aber statt dessen oder zusätzlich auch eine Anzeigeeinrichtung steuern, falls Anzeigeaufgaben gelöst werden sollen.

Damit möglichst wenig Energie verlorengelassen, empfiehlt sich die Verwendung einer Kaltlichtquelle, insbesondere einer Halogenlampe, der zusätzlich ein Wärmefilter vorgesetzt sein kann. Auch ist es empfehlenswert, die Kaltlichtquelle mit Gleichspannung zu speisen, d. h. zwischen die Lichtquelle und eine Wechselstromquelle einen Gleichspannungswandler einzuschalten.

Nach einer besonderen Ausbildung der Erfindung wird das zu applizierende Licht aus einem begrenzten Farbspektrum ausgewählt. Kommt es nämlich darauf an, nur eine sehr dünne Schicht des Gegenstandes, insbesondere deren Oberfläche, zu bestrahlen, empfiehlt sich die Verwendung eines UV- und Blaufilters mit Lichtenergie insb. zwischen etwa 320 und 450 nm Wellenlänge im Strahlengang. Ist eine Melamin-Detektion des Absorptionswertes brauner Haut vorgesehen, empfiehlt sich ein Grünfilter. Ein gelbes Farbfilter empfiehlt sich für die Bestrahlung tieferer Gewebeschichten und Rotfilter, die bis in den IR-A-Bereich um etwa 900 nm reichen, werden vor allem für die Behandlung tieferer Schichten im Gegenstand, beispielsweise tiefere Gewebeschichten bis zu etwa 5 cm von der Gewebeoberfläche aus, angewendet.

Die Lichtenergiemenge richtet sich also nicht nur nach der Zeit, Dauer und Intensität des Lichtes, sondern auch nach dem Frequenzbereich, aus dem es stammt, d. h. der Lichtfarbe. Im Falle der Ausnutzung der Heilwirkung von polarisiertem Licht empfiehlt sich eine Energiemenge im Bereich von 100 mJ/cm² bestrahlter Fläche. Sofern tiefere Gewebeschichten bestrahlt werden, kann eine auch erheblich höhere Lichtmenge angewendet werden.

Das polarisierte Licht ist vorzugsweise linear und zirkular polarisiert. Absorbiert das bestrahlte Gewebe die Photonen nicht, so erfolgt aufgrund unterschiedlicher Brechungsindizes und der dadurch bedingten unterschiedlichen Lichtgeschwindigkeit eine Drehung der Polarisationssebene des

Lichtes. Für Wellenlängen, bei denen der betreffende Gegenstand absorbiert, wird der Lichtstrahl elliptisch polarisiert und die Hauptachse der Ellipse gedreht. Anisotrope Gewebe machen aus linear polarisiertem Licht im Durchlässigkeitsbereich eine eliptische Polarisation. Ein Unterfall ist das eliptisch und zirkular polarisierte Licht.

Es empfiehlt sich bei Anwendung linear polarisierten Lichts die Anwendung eines Neigungswinkels der Kontaktfläche, d. h. eines Eintrittswinkels des Lichtes vom Lichtleiter in den Gegenstand, beispielsweise Hautgewebe; sofern der Neigungswinkel zwischen etwa 50 und 60 Grad aufweist, wird eine besonders große Verlustarmut an der Kontaktfläche erzielt.

Für viele Anwendungsfälle empfiehlt es sich, wenn der Applikator mit seiner mit dem Gegenstand in Kontakt tretenden Kontaktfläche vom Lichtleiter abtrennbar ist. Zu diesem Zweck ist es zweckmäßig, den Applikator mittels einer Kupplung mit einem Handgriff zu verbinden, so daß der Applikator nach dem Endkuppeln abgenommen und beispielsweise sterilisiert werden kann.

Das Polarisationsfilter ist zweckmäßigerweise zwischen der Kontaktfläche und dem Lichtleiterende angeordnet, was nach einer besonderen Ausbildung der Erfindung in Form einer Kappe geschieht, die zwischen das Lichtleiterende und den Applikator so eingefügt wird, daß der von der Stirnseite des Lichtleiterendes ausgehenden Lichtstrahl durch das Polarisationsfilter auf das Kontaktelement fällt, welches die Kontaktfläche an der Außenseite des Applikators bildet. Für manche Anwendungsfälle kann das Polarisationsfilter auch abgenommen sein.

Bei anderen Anwendungsfällen, bei denen es auf eine möglichst punktförmige Applikation des Lichtes ankommt, empfiehlt es sich, im Bereich zwischen dem Lichtleiterende und der Kontaktfläche eine Fokussiereinrichtung anzuordnen. Hierdurch können beispielsweise Akupunktur-Punktstimulationen erreicht werden, da eine hohe Photonendichte von mehr als beispielsweise 800 mW/cm² in allen Farbtemperaturen auf der Hautoberfläche erzielbar ist.

Ein bevorzugtes Ausführungsbeispiel der Erfindung wird nun anhand der Zeichnung erläutert. Darin zeigen:

Figur 1 eine schematische Darstellung - teilweise im schematischen Schnitt - einer erfindungsgemäßen Vorrichtung und

Figur 2 einen vergrößerten Teilschnitt des Applikators im Bereich des Lichtleiterendes.

Bei der erfindungsgemäßen Vorrichtung wird als Lichtquelle 3 eine Halogenlampe verwendet. Die Steuerung, darunter das Ein- und Ausschalten

der Lichtquelle 3, erfolgt über die Dosiereinrichtung 2, welcher eine Spannungsquelle 1 vorgeschaltet ist, welche die Netz-Wechselspannung in Gleichspannung umformt. Die Dosiereinrichtung 2 wird von einer Steuereinrichtung CONTR 20 gesteuert. Das von der Lichtquelle 3 ausgesandte weiße Licht durchtritt ein Wärmefilter 4, welches Wärmestrahlen ausfiltert. Danach gelangt das Licht L durch eine Sammellinse 5 und ein Farbfilter 7d, beispielsweise ein Blaufilter, das mit anderen Farbfiltern, beispielsweise dem Gelbfilter 7a, auf einer als drehbarer Karussellplatte dienenden Mehrfiltereinrichtung 6 angeordnet ist, so daß wahlweise eines von beispielsweise vier verschiedenen Farbfiltern in den Strahlengang des Lichts L eingeschaltet werden kann. Der Antrieb der Mehrfilteranordnung 6 kann manuell, aber auch automatisch durch eine Steuereinrichtung erfolgen. Das Licht tritt als Applikationslicht L in einen Lichtkoppler 8 in Form eines Lichtleiters ein, welcher das Licht zu einer Anschlußbuchse 9 des von dem Gehäuse 23 umgebenden Geräts leitet. Von dort tritt das Licht über die Stirnseite des Lichtkopplers 8 und die Stirnseite des Lichtleiters 10, insb. eines Glasfaserkabels, in diesen ein. Das Licht L wird dann bis zu dem anderen Lichtleiterende 10b geleitet und tritt dort über das Polarisationsfilter 16, welches eines insb. lineare Polarisierung vornimmt, in das Kontaktelement 17 ein, um über die Kontaktfläche K in den Gegenstand G, beispielsweise organisches Gewebe, jedenfalls an der Grenzfläche einzudringen.

Das Polarisationsfilter 16 besteht hier aus einem dünnen Polarisationsfilterblättchen aus Glas- oder Kunststoffolie, welche beidseitig mit einem Glas- oder Kunststoffblättchen abgedeckt ist. Diese drei Segmente werden von einer Hülse 16a gehalten, die als Kappe auf das Lichtleiterende 10b dann aufsteckbar ist, wenn der Applikator K mit seiner metallischen Hülse 15 und dem aus insb. Glas bestehenden Kontaktelement 17 abgezogen ist.

Weitere Anwendungsfälle sind beispielsweise das durch Licht polymerisierende Aushärten von Zahnfüllmaterial, wie dem unter dem Warenzeichen ESTILUX bekannten lichthärtenden Einkomponenten-Composite mit glaskeramischem Füllstoff und/oder hochdispersem Siliziumdioxid. In diesem Fall kann auf das Polarisationsfilter verzichtet werden.

Die nicht auf den Gegenstand übergegangene Lichtmenge, also ein Teil des Applikationslichts L, gelangt durch Reflexion, Streuung oder Beugung oder dergleichen insb. über den gleichen Lichtleiter 10 wieder zurück in das Ausgangsgerät mit dem Gehäuse 23. Zu diesem Zweck empfiehlt es sich, eine Abzweigung 10a im Lichtleiter vorzusehen, so daß ein Lichtleiterteil 10c zu einer anderen Buchse 9a führt, die über einen anderen Lichtkoppler 8a mit dem Sensor 18 bzw. der dort angeordneten

Photodiode verbunden ist. Der vom Sensor ermittelte nicht auf den Gegenstand G übertragene und auch nicht anderweitig verlorengegangene Anteil des Primär- bzw. Applikationslicht führt zu einem Ausgangssignal, welches dem Komparator COMPAR 19 zugeleitet wird. Hier erfolgt nun ein Vergleich mit einem Vergleichswert, beispielsweise einem IST-Wert, um in Abhängigkeit vom Unterschied zwischen diesen beiden Werten die Steuereinrichtung CONTR 20 zu beeinflussen, die ihrerseits auf die Dosiereinrichtung 2 einwirkt, um die richtige Dosierung vorzunehmen.

Für viele Anwendungsfälle empfiehlt sich die Verwendung einer Anzeigeeinrichtung DISPL 22 beispielsweise dann, wenn Messungen mittels Lichtstrahlen am Gegenstand G über die Kontaktfläche K vorgenommen werden sollen.

Die Anzeigeeinrichtung 22 kann jedoch auch zur Anzeige verschiedener Programme dienen, welche beispielsweise durch Einstecken von Datenträgern, wie Disketten oder Memory-Karten, in die Datenträger-Aufnahmeeinrichtung 21a ausgewählt werden. Die Programmauswahleinrichtung 21 kann darüber hinaus einen Datenspeicher MEM 21b aufweisen, in dem bestimmte Programme eingespeichert sind, die dann durch auf den Datenträgern befindliche Befehle abgerufen und dem Komparator 19, der Anzeigeeinrichtung 22, dem Sensor 18, der Steuereinrichtung 20 und/oder der Mehrfiltereinrichtung 66 bzw. der Antrieb zugeführt zu werden.

Darüber hinaus kann eine Programmauswahl und/oder Einschalten bzw. Ausschalten der Dosiereinrichtung 2 auch mittels eines Schalters 13 bzw. Tasters erfolgen, welcher im Handgriff 12 angeordnet ist und über eine insbesondere elektrische Leitung 11 mit der entsprechenden Einrichtung, beispielsweise dem Sensor 18 oder (nicht dargestellt) der Dosiereinrichtung 2, in Verbindung steht. Mit dem Schalter 13 können daher in unmittelbarer Nähe des Applikators A sowohl Programmwahl als auch Programmablauf von der Bedienungsperson gesteuert werden. Dabei besteht auch die Möglichkeit, eine Anzeigeeinrichtung im Handgriff selbst unterzubringen.

Das Anwendungsgebiet der erfindungsgemäßen Vorrichtung ist außerordentlich vielseitig. So sind analytische Untersuchungen an und/oder in Gegenständen möglich. Darüber hinaus kann die Vorrichtung zur heilenden Behandlung von Geweben Anwendung finden. Auch technische Anwendungen wie das oben schon erwähnte Aushärten von lichterhärtendem Material sind möglich, ebenso wie die Anwendung als Detektor, um beispielsweise pulpäre Irritationen im Zahnbereich zu ermitteln; im letztgenannten Fall wird zweckmäßigerweise ein Gelbfilter angewendet und die Kontaktfläche K auf die Kaufläche des Backenzahn oder die Frontflä-

che eines Schneidezahns angelegt, wodurch beispielsweise der Pulsschlag der Pulpa und auch kariöse Erscheinungen über Vergleichswerte bzw. Vergleichsprogramme von gesunden Pulpen feststellbar sind. Mit anderen Worten: Das Gerät dient hier auch als Diagnosehilfe.

Ferner sind Depressionsbehandlungen über Augenbestrahlungen ebenso möglich wie kosmetische Anwendungen, beispielsweise auch die Behandlung von Akne.

Der Sensor 18 dient zum Erfassen der vom Gegenstand nicht absorbierten und dort reflektierten bzw. von dort zurückgesandten Lichtstrahlen. Durch Vergleich der über den Lichtkoppler 8a aufgenommenen Lichtstrahlen und mit in den Lichtkoppler 8 abgesandten Lichtstrahlen kann der Differenzwert ermittelt werden. Die Multiplikation des auf die betreffende Einrichtung normierten Differenzwerts mit der Applikationszeit der Lichtstrahlen ergibt die vom Gegenstand absorbierte Dosis, und zwar auf automatische Weise, was einen erheblichen technischen Fortschritt sicherstellt.

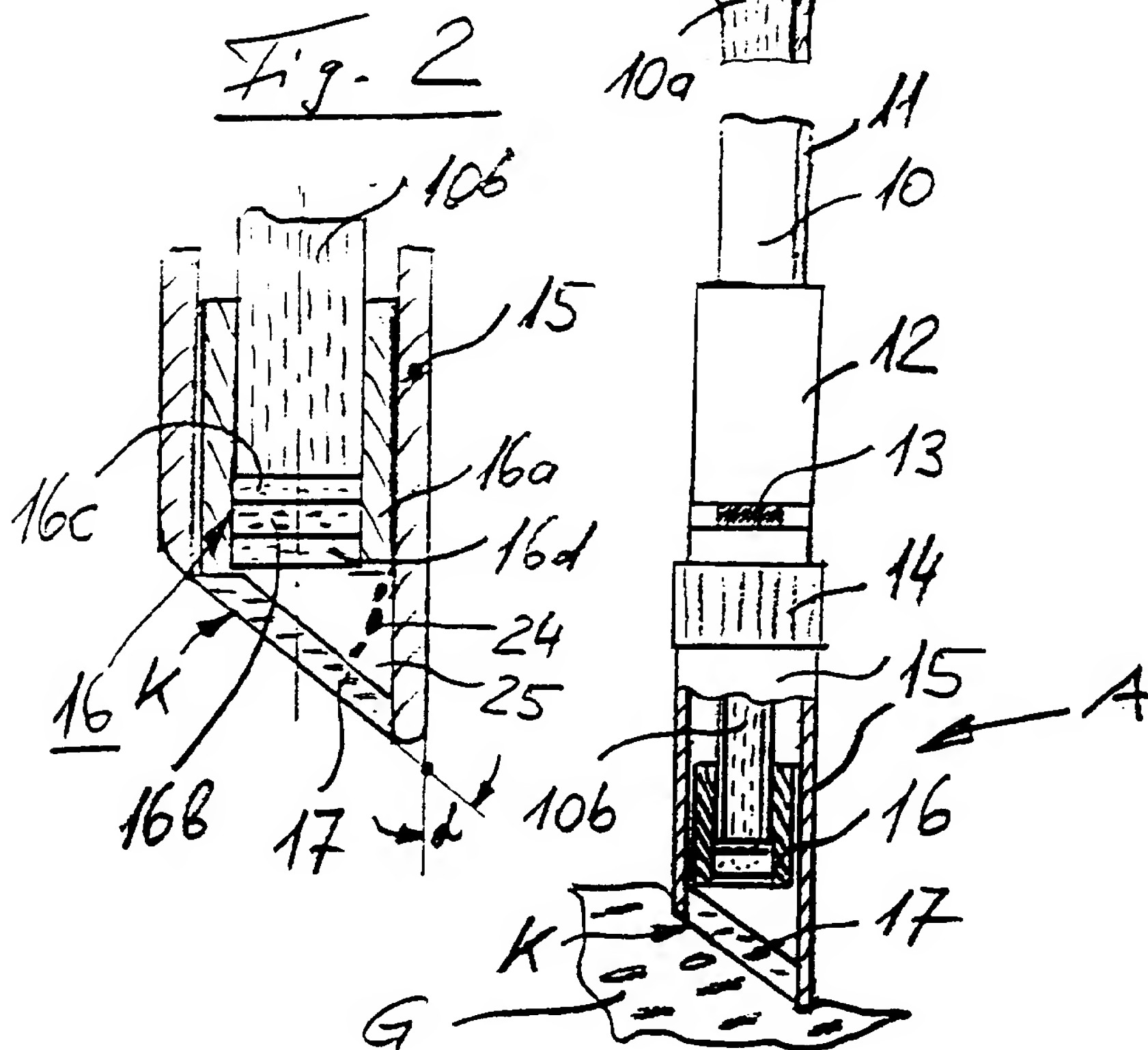
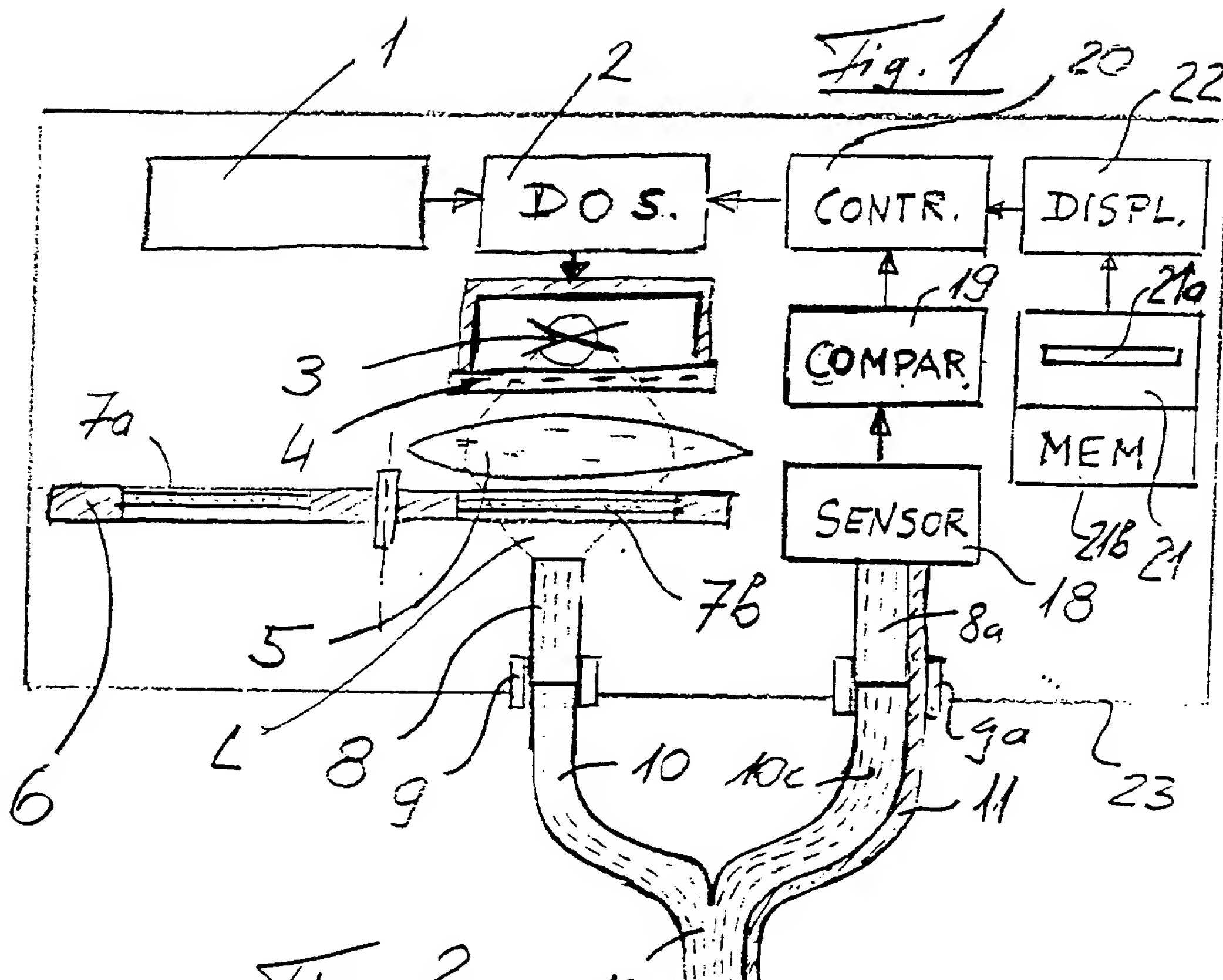
Durch Anwendung von Blaulicht mit evtl. UV-Anteilen werden Zellmembranen durchlässiger, was Wachstumsfaktoren stimuliert. Die Enzyme in den Mitochondrien werden aktiviert zur ATP-Bildung. Die SH-Enzyme werden reduziert. Bei Anwendung von Rotlicht, ggf. ergänzt durch Gelblicht und IR-A-Licht, wird der Kohlenhydrat-, Eiweiß- und Fettstoffwechsel stimuliert und können ebenfalls Enzyme in den Mitochondrien aktiviert werden, was zur Wundheilung bzw. Schmerzreduzierung Anlaß gibt. Die bei der Erfindung anwendbare polarisierte Photonenapplikation synchron zur Energierelevanz ist ein fortschrittliches Hilfsmittel beispielsweise in der Dentalpraxis.

Es empfiehlt sich, den Applikator A über einen biegbaren Lichtleiter 10 mit dem Gehäuse 23 zu verbinden, so daß die Bedienungsperson den Applikator A mit der Kontaktfläche K auch an sonst schwierig zugängliche Stellen in beispielsweise Körperhöhlen, wie der Mundhöhle, einführen und dediziert an die gewünschte Behandlungs- bzw. Untersuchungsfläche anlegen kann.

Außerdem kann es zweckmäßig sein, in der Umgebung der Kontaktfläche K bzw. im Raum 25 einen Reflektor 24, z. B. eine reflektierende Beschichtung, poliertes Metall oder eine besonders konstruierte Reflektorstruktur, anzuordnen, um vom Gegenstand G oder der Kontaktfläche K reflektiertes Licht wieder in das Lichtleiterende 10b, d. h. in die Lichtleiterfasern, einzukoppeln, damit das vom Gegenstand G reflektierte Licht möglichst verlustfrei am Sensor 18 eintrifft.

Patentansprüche

1. Vorrichtung zum Applizieren von Lichtenergie, mit einer Lichtquelle (3), mit einem Lichtleiter (10), mit einem Applikator (A) zum Applizieren des Applikationslichts auf dem betreffenden Gegenstand (G) über eine Kontaktfläche (K) des Applikators, mit einem Sensor (18), der über einen Lichtleiter vom Gegenstand ausgehendes Licht erfaßt, mit einem Komparator (19), der dieses erfaßte Licht oder ein davon abgeleitetes Signal mit einem Vergleichswert vergleicht und mit einer Steuereinrichtung (20), die vom Vergleichsergebnis abhängig eine Ansprech- und/oder eine Anzeigeeinrichtung (22) steuert, 5
dadurch gekennzeichnet,
 daß der Lichtleiter (10) über die Kontaktfläche (K) des Applikators (A) auf den Gegenstand (G) nicht übertragenes Applikationslicht (L) zum Sensor (18) zurückleitet, der dieses nicht auf den Gegenstand übertragene, zurückkehrende Applikationslicht (L) zum Beeinflussen der Steuereinrichtung (20) und/oder einer als Ansprechereinheit dienenden Dosiereinrichtung (2) für die Lichtquelle (3) erfaßt. 10
2. Vorrichtung nach Anspruch 1, 15
dadurch gekennzeichnet,
 daß als Lichtquelle (3) eine Kaltlichtquelle verwendet ist, der insbesondere ein Wärmefilter (4) vorgesetzt ist. 20
3. Vorrichtung nach Anspruch 1 und 2, 25
dadurch gekennzeichnet,
 daß in den Lichtstrahlengang zwischen der Lichtquelle (3) und dem Lichtleiter (10) ein Farbfilter (7, 7a, 7b) eingefügt ist. 30
4. Vorrichtung nach einem der vorhergehenden Ansprüche, 35
dadurch gekennzeichnet,
 daß der Applikator (A) mittels einer Kupplung (14) mit einem Handgriff (12) verbindbar ist, zu dem der Lichtleiter (10) führt, und daß der Handgriff (12) einen Schalter (13) oder Taster aufweist, welcher über einen elektrischen Leiter (11) mit der Steuereinrichtung (20) der Dosiereinrichtung (2), der Anzeigeeinrichtung (22), einem Antrieb für die Mehrfiltereinrichtung (6) und/oder einer Programmauswahleinrichtung (21) in Steuerverbindung steht. 40
5. Vorrichtung nach einem der vorhergehenden Ansprüche, 45
dadurch gekennzeichnet,
 daß der Applikator (A) ein die Kontaktfläche (K) bildendes transparentes Kontaktelement (17) aufweist, daß unter einem Neigungswinkel (α) zur Längsachse des Applikators (A) bzw. Handgriffs (12) geneigt ist. 50
6. Vorrichtung nach einem der vorhergehenden Ansprüche, 55
dadurch gekennzeichnet,
 daß das innerhalb des Applikators (A) befindliche Lichtleiterende (10b) stirnseitig von einem Polarisationsfilter (16) abgedeckt ist.
7. Vorrichtung nach einem der vorhergehenden Ansprüche, 60
dadurch gekennzeichnet,
 daß eine Programmauswahleinrichtung (21) eine Datenträger-Aufnahmeeinrichtung (21a) sowie einen Datenspeicher (21b) aufweist.
8. Vorrichtung nach einem der vorhergehenden Ansprüche, 65
dadurch gekennzeichnet,
 daß die Dosiereinrichtung (2) die Dauer und/oder Intensität des von der Lichtquelle (3) ausgesandten Lichts dosiert.
9. Vorrichtung nach einem der vorhergehenden Ansprüche, 70
dadurch gekennzeichnet,
 daß in der Nähe des Kontaktelements (K) ein Reflektor (24) zum Reflektieren des vom bestrahlten Gegenstand (G) reflektierten Lichts zurück in den Lichtleiter (10) angeordnet ist.
10. Vorrichtung nach einem der vorhergehenden Ansprüche, 75
dadurch gekennzeichnet,
 daß der Applikator (K) mit einer Fokussiereinrichtung versehen ist, welche die Lichtstrahlen auf einen im wesentlichen punktförmigen Bereich der Kontaktfläche (K) fokussiert.





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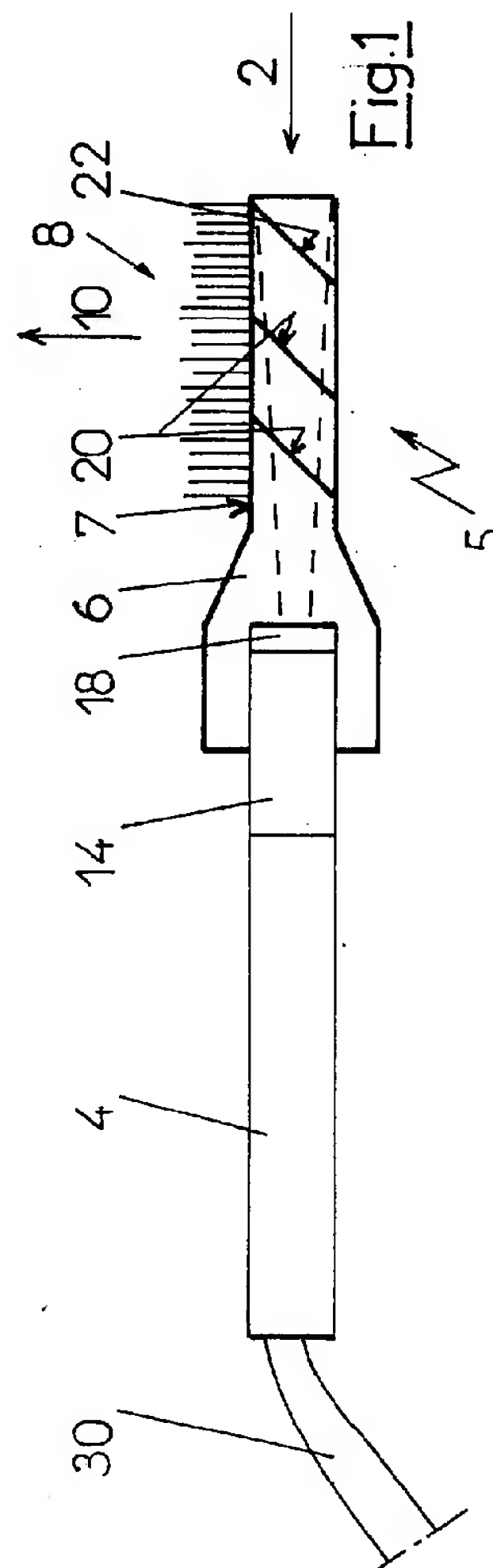
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(54) **Dental hygiene appliance.**

(57) A dental hygiene appliance for brushing teeth composed of a handle (4); a brushing head (5) connected to the handle (4) and a set of tooth brushing bristles (8) projecting in a given direction from the head (5); a source of monochromatic radiation having a given wavelength (14) e.g. laser; and elements (20,22) for directing the radiation from the head (5) in a direction having at least a component in the given direction; wherein the elements for directing radiation are structurally separate from the bristles (8).



BACKGROUND OF THE INVENTION

The present invention relates to dental hygiene appliances, and particularly toothbrushes equipped to apply radiation to tooth surfaces.

It has been proposed in the art to equip a toothbrush with a light source which can illuminate the region being brushed. The purpose of such devices is to aid the brushing operation by better illuminating the portion of the teeth being brushed. A device of this type is disclosed in U.S. Patent No. 4,779,173, where the toothbrush bristles are plastic filaments which conduct radiation from a light source in the handle of the brush. This patent also discloses earlier prior art including a dental cleaning apparatus in which the head portion or bristle holding portion is eliminated.

It is also known in the art that laser radiation can have a variety of beneficial effects on teeth.

U.S. Patent No. 5,030,090 discloses a toothbrush having a bundle of bristles constituted by optical fibers which are coupled to a semiconductor laser. The fibers constitute the bristles of the toothbrush. This patent discloses that the radiation produced by semiconductor laser can be used for treating or preventing gingivitis and other oral diseases, and specifically can serve to reduce pain and inflammation and to improve blood circulation.

One of the characteristics of the device as disclosed in the above-cited patents is that they employ filaments which are capable of functioning as both optical fibers and brushing bristles. One problem with devices of this type is that filaments which are capable of functioning as optical fibers can not be given the mechanical characteristics required to permit them to function in an optimum manner as brushing bristles. In particular, if the filaments must be fabricated to function as optical fibers, it will prove difficult to give them the durability desired for brushing bristles.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a novel dental hygiene appliance which applies radiation having a selected wavelength to tooth surfaces while those surfaces are being brushed.

Another object of the invention is to provide an appliance of this type in which the toothbrush bristles are employed only for brushing, and may therefore be selected solely on the basis of the characteristics required for performing that function.

Another object of the invention is to employ such an appliance in a manner to enhance the effectiveness of the brushing action, possibly with the aid of chemical product which facilitates observation and/or removal of one or more substances of the type which form deposits on teeth.

The above and other objects are achieved, ac-

ording to the present invention, by a dental hygiene appliance for brushing teeth comprising: a handle; a brushing head connected to the handle and a set of tooth brushing bristles projecting in a given direction from the head; a source of monochromatic radiation having a given wavelength; and means for directing the radiation from the head in a direction having at least a component in the direction; given wherein the means for directing radiation are structurally separate from the bristles.

Objects according to the invention are further achieved by supplying with the appliance a chemical product which is capable and/or facilitating removal, of a substance which forms deposits on teeth and when that substance is irradiated by the radiation having a given wavelength. Then, since the brushing action is performed on, and the radiation is being applied to, substantially the same tooth areas, the brushing action in the presence of that chemical product will facilitate thorough cleaning of the teeth.

BRIEF DESCRIPTION OF THE DRAWING

Figure 1 is a simplified side elevational view, partly in cross section, illustrating the basic components of an embodiment according to the present invention.

Figure 2 is an end elevational view in the direction of the arrow 2 of Figure 1.

Figure 3 is a detail view illustrating a modified version of a portion of the appliance of Figure 1.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The basic components of an appliance according to the present invention include, as shown in Figures 1 and 2, a handle 4 and a brushing head 5. Brushing head 5 is constituted by a body 6 having a base surface 7 from which a set of tooth brushing bristles 8 project. The composition and form of bristles 8, and the manner in which bristles 8 are secured to body 6, conform to conventional practice in the toothbrush art.

Appliances according to the present invention are further provided with means for directing monochromatic radiation of a selected type from body 6 in the direction of arrow 10, which is generally parallel to the direction in which bristles 8 project from body 6. However, in appliances according to the invention, the radiation is not guided by the bristles themselves, but is emitted generally via base surface 7 of body 6.

In the embodiment illustrated in Figures 1 and 2, handle 4 is provided with a laser device 14, for example a semiconductor laser, and brushing heads 5 is provided with a lens 18, one or more semitransparent mirrors 20 and a fully reflecting mirror 22. Radiation produced by laser 14 may be in the form of a small diameter collimated beam extended along an axis

corresponding to the longitudinal axis of handle 4 and head 5. Mirrors 20 and 22 may be oriented at an angle of 45° to the beam axis and lens 18 is constructed and arranged to give the laser radiation beam a slightly diverging form such that the beam will diverge to an area essentially coextensive with the area occupied by mirror 22.

Body 6 may itself be made of a plastic which is transparent to the laser radiation so that portions of the radiation will be reflected in the direction 10 by mirrors 20, and the remaining radiation will be reflected by mirror 22. The optical system constituted by lens 18 and mirrors 20, 22 is arranged to cause radiation to traverse an area at least approximately coextensive with the area covered by the tips of bristles 8. However, the radiation area may, depending on the particular operations to be performed, extend over a smaller or larger area.

In the embodiment illustrated in Figures 1 and 2, handle 4 includes a power cord 30 which may be plugged into a wall outlet in order to supply operating power to laser 14. Alternatively, handle 4 could be constructed as a holder for a replaceable or rechargeable battery which supplies the necessary operating power. In addition, in the embodiment illustrated in Figures 1 and 2, brushing head 5 is readily detachable from handle 4. This allows a plurality of brushing heads 5, each used by a different individual, to be mounted on head 4 for use. In addition, as shown in Figures 1 and 2, lens 18 may form a unit with head 2, so that each of the brushing heads 5 need not be provided with its own lens. This would reduce the cost of manufacturing each head 5.

Figure 3 shows an alternative embodiment of the brushing head, which can be constituted by two plastic pieces 34 and 36 joined together along a plane 40 having a series of surfaces which are inclined at an angle of 45° to the axis of the radiation emitted by laser 14. Plane 40 is made to be a reflecting surface by an appropriate coating or finishing process. In Figure 3, the bristles 8 are not shown, for the sake of simplicity.

The radiation provided in an appliance according to the present invention has a wavelength as well as an intensity, selected to have a desired effect on one or more substance which may become deposited on tooth surfaces and which it is desired to remove. Typical substances of this type include bacteria, tartar and calculus, all of which contribute to or are precursors, to tooth decay. In addition, when certain chemical products are brought into contact with one or another of these substances, the application of radiation having an appropriate wavelength and energy content can render the substance or substances visible and/or can help to remove those substances from tooth surfaces.

Thus, in accordance with the invention, an appliance of the type described above is used in cooper-

ation with such a chemical product, which may be incorporated into a toothpaste, tooth gel or tooth powder, formulated and marketed for use specifically with the appliance.

By way of example, one of the purposes of tooth brushing is to remove bacteria which have collected on tooth surfaces, frequently in pits and fissures in the tooth enamel. It is known that regardless of the care exercised and time spent in a brushing session, some of the bacteria deposits may not be dislodged and removed from the tooth surfaces. It is also known that there are chemical products, known as disclosing solutions, which can make any deposited bacteria visible. There are other chemical products, which may be preferable to the conventional disclosing solutions, which will react with bacteria in such a manner as to render the bacteria visible in the presence of radiation having a certain wavelength. Such product can be provided as an ingredient of a special toothpaste, tooth gel or tooth powder supplied with the appliance according to the invention.

When such a tooth cleaning preparation is employed, the chemical product will render any existing bacteria visible under the radiation produced by source 14, so that brushing can be continued until the user can observe that all bacteria have been removed from all visible tooth surfaces. While it would be more difficult to carry out this procedure on lingual tooth surfaces, this would be possible, if brushing were carried out while viewing those surfaces with a mirror.

In further accordance with the invention, the chemical product may be selected to render tartar or calculus visible, while the appliance is then utilized to remove those materials. Possibly, special brush heads with appropriate bristles could be provided for this purpose.

In further accordance with the invention, use may be made of a product which reacts with bacteria, tartar or calculus in such a manner that radiation of an appropriate wavelength will have the effect of removing the bacteria, tartar or calculus, or of altering the nature of the bacteria, tartar, or calculus, as by softening it, in manner to facilitate complete removal by the brushing action.

According to one exemplary embodiment of the invention, the chemical product consists of or contains nigrosin and the radiation source produces radiation at a wavelength of between 1 μ and 6 μ . The radiation source may be, for example, an Nd:YAG laser. The source will be adjusted to emit radiation at an energy level selected on the basis of the expected concentration of nigrosin in the material to be treated.

Nigrosin will stain, for example, cariogenic bacteria or streptococcus faecalis black so that this bacteria, or any other substance absorbing nigrosin, will readily absorb the laser radiation.

According to another possibility, the chemical

product can be sudan red as a vital stain when the radiation source is an argon laser.

In both cases, the radiation energy density could be made sufficiently high to directly vaporize the stained substance. For example, in the case where streptococcus faecalis is stained with nigrosin and irradiated by an Nd:YAG laser, this effect can be achieved with an energy density of the order of 10J/cm².

While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof, The accompanying claims are intended to cover such modifications as would fall within the true scope and spirit of the present invention.

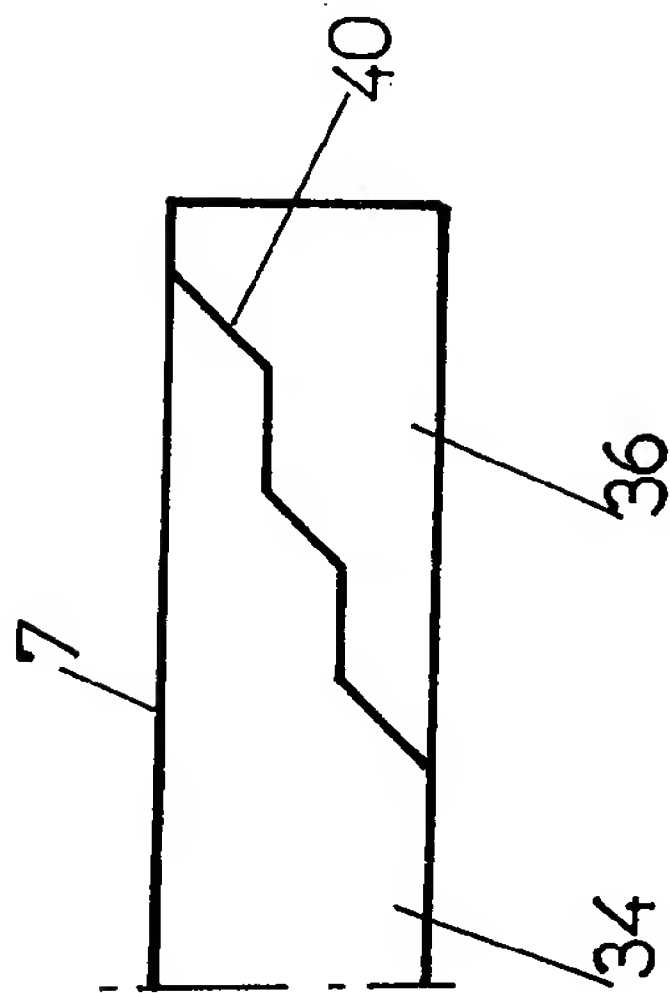
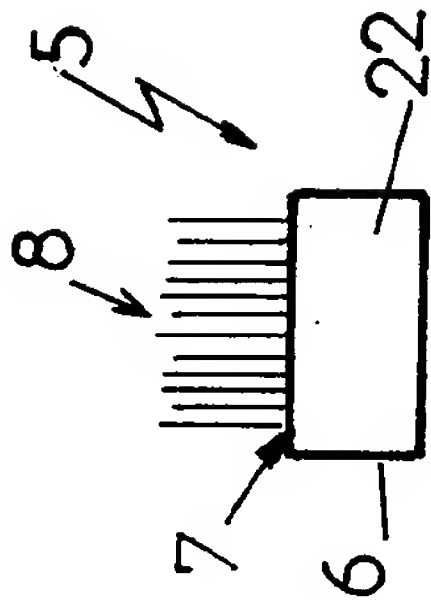
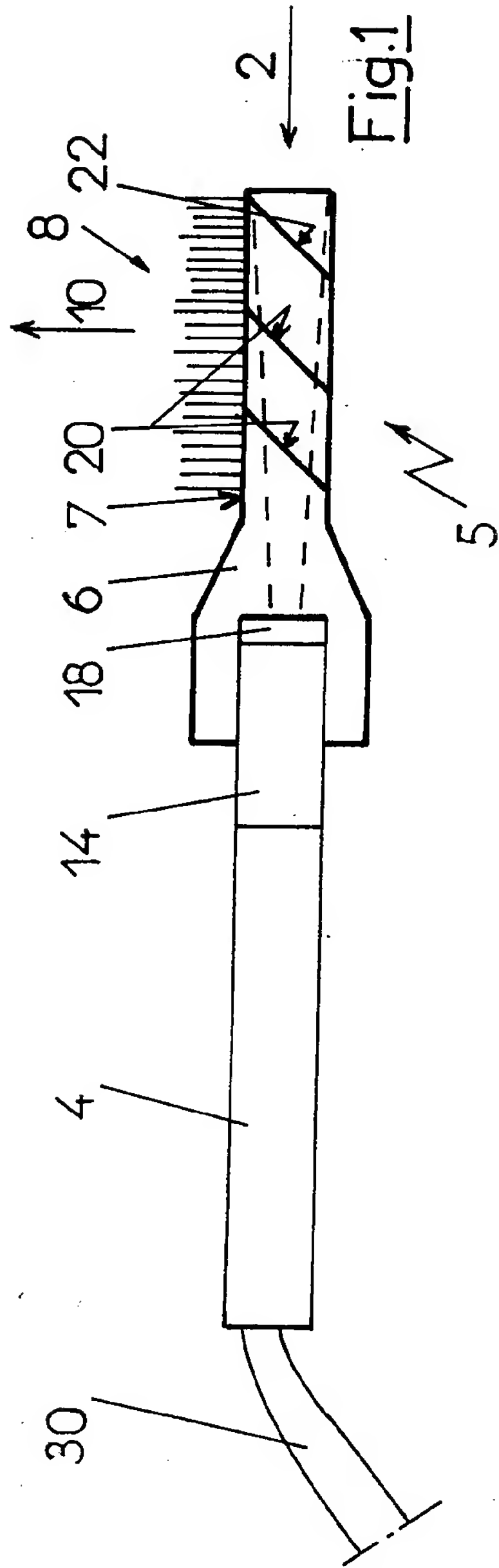
The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, rather than the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

Claims

1. A dental hygiene appliance for brushing teeth comprising:
 - a handle;
 - a brushing head connected to said handle and a set of tooth brushing bristles projecting in a given direction from said head;
 - a source of monochromatic radiation having a given wavelength; and
 - means for directing the radiation from said head in a direction having at least a component in the given direction;
 - wherein said means for directing radiation are structurally separate from said bristles.
2. An appliance as defined in claim 1 wherein said bristles are made of a material selected to perform an effective brushing action on teeth.
3. An appliance as defined in claim 2 wherein said bristles are made of nylon or a natural material.
4. An appliance as defined in claim 1 wherein said means for directing radiation comprise optical components in said head for directing the radiation at least partly around said bristles.
5. An appliance as defined in claim 1 further comprising means in said handle for delivering the radiation to said means for directing radiation.
6. An appliance as defined in claim 5 wherein said means in said handle comprise a radiation

source.

7. An appliance as defined in claim 6 wherein said means in said handle comprise a battery constituting a power source for said radiation source.
8. An appliance as defined in claim 6 wherein said radiation source is a laser.
9. An appliance as defined in claim 5 wherein said brushing head is readily detachable from said handle.
10. An appliance as defined in claim 9 wherein said means in said handle comprise a radiation source.
11. An appliance as defined in claim 10 wherein said means in said handle comprise a battery constituting a power source for said radiation source.
12. An appliance as defined in claim 10 wherein said radiation source is a laser.
13. An appliance as defined in claim 1 wherein radiation having a given wavelength is capable of rendering visible a substance present on a tooth.
14. An appliance as defined in claim 1 wherein radiation having the given wavelength is capable of rendering visible a substance present on a tooth when the substance has been contacted by a given chemical product, in combination with a supply of the given chemical product.
15. The combination as defined in claim 14 wherein said supply of the given chemical product comprises a mass of toothpaste containing the given product.
16. An appliance as defined in claim 1 wherein radiation having a given wavelength is capable of removing a substance present on a tooth.
17. An appliance as defined in claim 1 wherein radiation having the given wavelength is capable of removing a substance present on a tooth when the substance has been contacted by given chemical product, in combination with a supply of the given chemical product.
18. The combination as defined in claim 17 wherein said supply of the given chemical product comprises a toothpaste containing the given product.





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 43 0014

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
X	WO-A-92 06671 (WIEDEMANN)	1-7, 13-15	A46B15/00
Y	* page 1, line 13 - page 9, line 5; figures *	8-11, 16-18	
Y	--- PATENT ABSTRACTS OF JAPAN vol. 016, no. 49 (C-0908)7 February 1992 & JP-A-32 051 207 (MATSUSHITA) * abstract *	8,16-18	
Y	--- US-A-3 667 454 (PRINCE) * claims; figures *	9-11	
A	--- US-A-3 261 978 (BRENMAN) * claims; figures *	1	
A,D	--- US-A-4 779 173 (CARR ET AL.)	1	
A,D	--- US-A-5 030 090 (MAEDA ET AL.)	1	
			TECHNICAL FIELDS SEARCHED (Int.Cl.5)
			A46B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 17 December 1993	Examiner Ernst, R
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons</p> <p>----- & : member of the same patent family, corresponding document</p>			

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Remarks:

A request for correction in the last line of claim 27 has been filed pursuant to Rule 88 EPC. A decision on the request will be taken during the proceedings before the Examining Division (Guidelines for Examination in the EPO, A-V, 3.).

(54) **Method and apparatus for generating bright light sources**

(57) A method and apparatus for generating bright light sources includes a first plurality of semiconductor lasers in which each of the first plurality of semiconductor lasers emits a beam of light of a first frequency; a second plurality of semiconductor lasers in which each of the second plurality of semiconductor lasers emits a beam of light of a second frequency; a first bundle of optical fibers for receiving the light from ones of the first plurality of semiconductor lasers and providing a first combined laser beam of a predetermined shape and having a cross-sectional area and a solid angle; a second bundle

of optical fibers for receiving the light from ones of the second plurality of semiconductor lasers and providing a second combined laser beam of a predetermined shape and having a cross-sectional area and a solid angle; and frequency responsive optics for combining the first and second combined laser beams into a composite laser beam, the composite laser beam having substantially the same product of cross-sectional area and solid angle as each of the first and second combined beams.

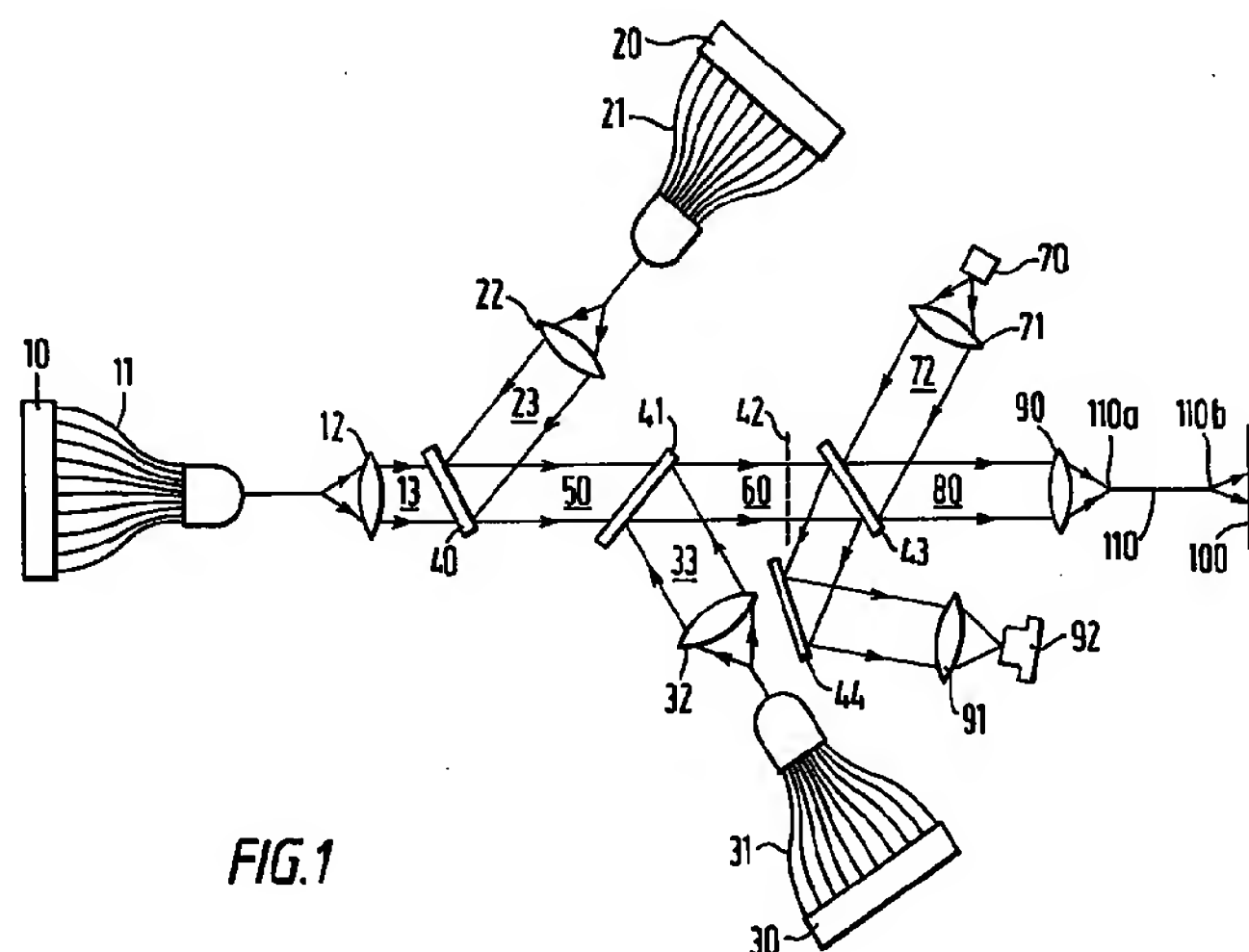


FIG. 1

EP 0 709 941 A1

Description

The present invention relates generally to a method and apparatus for generating bright light sources and has particular, although not exclusive relevance to a method and apparatus for generating bright light sources using semiconductor lasers of different wavelengths to perform medical laser applications.

In many applications, particularly medical laser applications, it is necessary to concentrate relatively high laser power onto a small area, e.g., for ablating or cutting tissue. This application of lasers requires that the laser source be of high brightness; that is, it must emit a high power beam of small area and small divergence. Brightness is directly proportional to the output power and inversely proportional to the source area and also to the solid angle of the light beam. (Brightness = power / (Source Area x Solid Angle)) It is therefore difficult to increase the brightness of a source by increasing the output power, since this also tends to increase the source area and/or the solid angle of the light beam such that the net effect on the brightness is relatively small. For example, suppose the object is to double the brightness of a particular laser that emits 1 watt of power into a certain solid angle. By simply taking another such laser and placing it adjacent the first, the result is two watts of power into essentially the same solid angle, but the total cross-sectional area of the new source is also twice as large such that the brightness of the combined source is essentially equal to the brightness of each separate laser (not double the brightness).

It has been proposed to use a plurality of laser diodes to provide a higher power laser diode light source from an optical fiber. An example of such a laser diode light source is disclosed in UK Patent Application GB 2256503A.

The prior art teaches to increase the brightness of a light source by using a polarized beam combiner on two beams of light of orthogonal polarizations from two laser diodes, thus combining the two beams into a single composite beam. The prior art further teaches to feed this composite beam into a fiber optic cable and then to bundle a group of these fiber optic cables to form a larger more powerful beam of light. This method suffers from a number of problems some of which include: the power output being limited by being able to combine only two laser diodes with each polarized beam combiner, and the multitude of polarized lasers and optics being very complex and expensive (this method requires a large number of beam combiner pairs to achieve a desired high power).

Thus there exists a need for a more efficient way to combine a plurality of laser diodes to form a relatively high brightness laser light source for performing medical laser applications.

It is thus an object of the present invention to provide a method of and an apparatus for generating a beam of bright light for medical laser applications.

It is another object of the present invention to provide a method of and an apparatus for generating a beam of bright light by efficiently combining a plurality of semiconductor lasers.

It is another object of the present invention to provide a method of and an apparatus for generating a beam of bright light by combining a plurality of semiconductor lasers of different frequencies.

It is yet another object of the present invention to provide a method of performing medical laser applications by generating a first laser beam of a first frequency, generating a second laser beam of a second frequency, combining the first and second laser beams into a composite laser beam then shining the composite laser beam into tissue.

Another object of the present invention is to provide an apparatus for generating a beam of bright light utilizing semiconductor lasers of different frequencies, bundles of optical fibers to form composite single frequency laser beams from the lasers of different frequencies respectively and frequency responsive optics for combining the composite laser beams of the different frequencies into a combined laser beam.

The foregoing objects are attained by the invention, which provides a method of and an apparatus for generating a bright light source including a first and a second plurality of semiconductor lasers in which each of the first and second plurality of semiconductor lasers respectively emits a beam of a first and second frequency. A first and a second bundle of optical fibers may respectively be used for receiving the light from ones of the first and second plurality of semiconductor lasers and for providing a first and a second combined laser beam of a predetermined shape and having a cross-sectional area and a solid angle. Frequency responsive optics are used for combining the first and second combined laser beams into a composite laser beam having substantially the same product of cross-sectional area and solid angle as each of the first and second combined beams.

The invention will next be described in connection with certain illustrated embodiments; however, it should be clear to those skilled in the art that various modifications, additions and subtractions can be made without departing from the spirit or scope of the claims.

For a fuller understanding of the nature and objects of the invention, an embodiment of the invention will now be described by way of example only with reference to the accompanying drawings in which:

FIG 1. illustrates one form of apparatus constructed in accordance with an embodiment of the present invention.

FIG. 1 depicts a bright light source in accordance with an embodiment of the invention such that the laser beam from the source is applied onto a working surface, such as tissue to be subjected to a medical laser treatment. The input power of each light source, as defined by a plurality of laser diodes, is of the order of many watts or tens of watts. The

produced composite beam is transmitted a relatively short distance (e.g., up to a few meters) such that the losses are very low or negligible, and therefore, the power of the composite beam is substantially equal to the sum of the powers of the input beams, again many watts or tens of watts.

5 The above technique for producing a bright light source is applicable generally with respect to a wide variety of light sources, but is particularly attractive in the case of laser diodes. It is known that laser diodes are small, efficient, easy to drive and modulate, very reliable, and of relatively low cost. However, the brightness of the presently known laser diodes, including the high power laser diodes, is generally far below the brightness of gas lasers or solid state lasers. Thus, the resulting power per unit area, per unit solid angle of laser light radiation generated by a laser diode, is insufficient for many medical laser applications.

10 The present invention exploits the above advantageous characteristics of laser diodes, and the further characteristic that laser diodes can be made to lase in a wide range of wavelengths. For example, the presently known high power laser diodes made of GaAlAs emit light in a range of 780 to 880 nm, and diodes made of InGaAs emit light in the range of 920 to 980 nm. The above-described techniques for increasing the brightness of a beam of light thus enables laser diodes to be used in applications, such as in medical laser applications, requiring high brightness outputs.

15 Thus, in the preferred embodiment of the invention, the source beam generators include a plurality of laser diodes of different wavelengths. In the described example, these generators include a first plurality of diodes 10 that produce laser beams of 780 nm, a second plurality of laser diodes 20 that produce laser beams of 860 nm, and a third plurality of laser diodes 30 that produce laser beams of 960 nm. It will be obvious to one skilled in the art that the generators could also be single high powered laser diodes of the previously mentioned frequencies. The power of each laser beam formed by combining the first plurality of laser diodes, the second plurality of laser diodes and the third plurality of laser diodes respectively is at least 10 watts, preferably about 15 watts. Thus the power of the composite output beam is approximately 45 watts, sufficient for use in many surgical laser applications. It will be appreciated that if higher powers are desired, more than three source beams can be combined in accordance with the present invention.

25 According to further features of the preferred embodiment, the plurality of beams are combined into the single composite beam such that the product of the cross-sectional area and the solid angle, of the single composite beam is substantially the same as the product in each of the source beams.

The apparatus illustrated in the drawing includes a first plurality of laser diodes 10, a second plurality of laser diodes 20 and a third plurality of laser diodes 30 generating laser beams of different wavelengths, e.g., of 780, 860 and 960 nm, respectively. As the laser energy from each plurality of laser diodes is emitted from a relatively wide area (typically about 10mm), the output from each plurality of laser diodes is directed to a fibre bundle 11, 21 and 31 respectively, which is tightly packed at the output end, e.g., to a circle of about 1 mm in diameter. Lenses 12, 22 and 32, respectively, collimate the light from each fibre bundle to produce three essentially collimated beams 13, 23 and 33, respectively.

30 The illustrated apparatus further includes frequency responsive optics in the form of a plurality of wavelength combiners 40, 41 for combining the plurality of light beams 13, 23 and 33, respectively, into a single composite beam. Thus, a first combiner 40 combines beams 13 and 23 into a composite beam 50; and a second combiner 41 combines beams 50 and 33 into a single composite beam 60.

40 In the illustrated example, combiners 40 and 41 are both dichroic elements, e.g., interference filters, which are highly transparent to one wavelength band and highly reflective to the other wavelength band. Thus, dichroic combiner 40 is highly transmissive with respect to the wavelength of laser beam 13 and is highly reflective with respect to the wavelength of laser beam 23; whereas combiner 41 is highly transmissive with respect to the wavelengths of both laser beams 13 and 23, and is highly reflective with respect to the wavelength of laser beam 33.

45 Each of the plurality of laser diodes 10, 20 and 30, should output at least one watt of power, preferably at least 10 watts of power in medical laser applications of the invention. In the illustrated example, each outputs 15 watts of power, so that the power of the single composite beam 60 is approximately 45 watts. This is normally sufficient to permit the laser beam to be used for many medical laser applications.

The illustrated apparatus further includes a safety shutter 42 in the path of the single composite beam 60, in order to selectively block the transmission of the single composite beam to the working surface 100.

50 The illustrated system further includes a fourth laser 70 which generates a laser beam of visible light and of low power, to serve as a visible aiming beam to be projected onto the working surface 100 in order to permit aiming the high powered composite beam 60. In the illustrated example, the aiming beam laser 70 is a laser diode generating a laser beam of 635 nm wavelength and of a few milliwatts of power. This laser beam is collimated by a lens 71 to produce a collimated beam 72 which is combined by a third dichroic combiner 43 with the high power composite beam 60 from the three pluralities of laser diodes 10, 20 and 30. Dichroic combiner 43 would thus be highly transmissive with respect to the wavelengths of the three pluralities of laser diodes 10, 20 and 30 but highly reflective with respect to the wavelength of the aiming laser 70. The output of the dichroic combiner 43 is thus a single composite beam 80 including the outputs of the three pluralities of laser diodes 10, 20 and 30 and the output of the aiming beam laser 70.

55 The output 80 of dichroic combiner 43 is then directed, via a focusing lens 90, into the inlet end 110a of a guiding optical fibre 110. The single composite beam exits from the outlet end 110b of the optical fibre 110 onto the working surface 100.

In the described apparatus, the combiners 40, 41 and 43, as well as the optics of the apparatus, are such that the product of the cross-sectional area and the solid angle of the single composite beam 80 outputted by combiner 43 is substantially the same as in each of the beams exiting from the plurality of laser diodes 10, 20 and 30 via their respective bundles.

Thus, the outlet end 110b of the guiding optical fibre 110 becomes a light source of high brightness, almost three times that of each of the pluralities of laser diodes, thereby enabling the use of laser sources, particularly laser diodes, for applications requiring high power and high brightness, such as medical laser applications.

While the dichroic combiner 43 is highly transmissive of the wavelengths of the three essentially collimated beams 13, 23 and 33 in the composite beam 60, a small fraction of the energy in the composite beam is reflected by the combiner 43. This small fraction reflected by combiner 43 is used for monitoring the power produced in the composite beam 80. For this purpose, the small fraction of the laser power reflected by combiner 43 is reflected by a mirror 44 through a focusing lens 91 onto a power detector 92 for measuring the laser energy so reflected from the combiner 43. Since the proportion of laser energy reflected by combiner 43 to the laser energy passing through the combiner 43 is known, depending on the characteristics of the combiner, the output of power detector 92 also provides a measurement of the total energy in the composite beam 80 applied, via optical fibre 110, onto the working surface 100.

It will be appreciated that whereas the illustrated system includes dichroic combiners, other types of wavelength combiners may be used for multiplexing the laser beams, e.g., a holographic element or grating, as known in the prior art. It will also be appreciated that whereas the illustrated apparatus shows combining three light sources, namely plurality of laser diodes 10, 20 and 30 together with the aiming beam laser 70, only two, or more than three, light sources could be combined, according to the requirements of a particular application.

It will thus be seen that the invention efficiently attains the objects set forth above, among those made apparent from the preceding description. In particular, the invention provides a method of and an apparatus for generating bright light sources using semiconductor lasers of different frequencies to perform medical laser applications. Those skilled in the art will appreciate that the configuration depicted in Fig. 1 efficiently and effectively attains a bright light source having a high power emitted from a tight radius into a confined solid angle.

It will be understood that changes may be made in the above construction and in the foregoing sequences of operation without departing from the scope of the invention. For instance it will be appreciated that the invention could be advantageously used in other applications requiring bright light sources, e.g., metal welding. It is accordingly intended that all matter contained in the above description or shown in the accompanying drawings be interpreted as illustrative rather than in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention as described herein, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

Claims

1. A method of producing a light source including the steps of:
generating a first laser beam of a first frequency;
generating a second laser beam of a second frequency and
combining said first and second laser beams into a composite laser beam.
2. A method according to claim 1 for performing medical laser applications including the step of:
shining said composite laser beam into tissue to perform medical laser applications.
3. The method according to claim 1 or 2, further including the steps of:
generating a third laser beam of a third frequency;
combining said third laser beam with said first and second laser beams into said composite laser beam.
4. The method according to anyone of claims 1 to 3, wherein
at least said first and second laser beams are generated by diode lasers.
5. The method according to any one of claims 1 to 4, wherein
at least said first laser beam, said second laser beam and said composite laser beam each has a cross-sectional area and a solid angle such that the product of the cross-sectional area and the solid angle of the composite laser beam is substantially the same as that of each of said first and second laser beams.
6. The method according to any one of claims 1 to 5, wherein
at least said first and second laser beams are combined into said composite beam by a dichroic combiner.

7. The method according to any one of claims 1 to 5, wherein
at least said first and second laser beams are combined into said composite beam by a holographic element.
8. The method according to any one of claims 1 to 5, wherein
at least said first and second laser beams are combined into said composite beam by a grating.
9. The method according to claim 4, wherein
said diode lasers are at least one watt of power each.
10. The method according to any one of claims 1 to 9, wherein
a small fraction of the composite beam is split-off and is directed to a power detector for measuring the power of said composite beam.
11. The method according to claim 3, wherein
said first laser beam is of a wavelength of 780 nm and of a power of at least 10 watts;
said second laser beam is of a wavelength of 860 nm and of a power of at least 10 watts; and
said third laser beam is of a wavelength of 960 nm and of a power of at least 10 watts.
12. The method according to any one of claims 1 to 11, wherein
an aiming beam of visible light and of a different wavelength than said first, second and third laser beams is also generated and combined into said composite beam.
13. The method according to claim 12, wherein
said aiming beam is of a wavelength of 635 nm and of a power of a few milliwatts.
14. The method according to any one of claims 1 to 13, wherein said composite beam is directed into said tissue by an optical fibre.
15. A bright light source including:
a first plurality of semiconductor lasers in which each of said first plurality of semiconductor lasers emits a beam of light of a first frequency;
a second plurality of semiconductor lasers in which each of said second plurality of semiconductor lasers emits a beam of light of a second frequency;
a first bundle of optical fibers for receiving the light from ones of said first plurality of semiconductor lasers and providing a first combined laser beam of a predetermined shape and having a cross-sectional area and a solid angle;
a second bundle of optical fibers for receiving the light from ones of said second plurality of semiconductor lasers and providing a second combined laser beam of a predetermined shape and having a cross-sectional area and a solid angle; and
frequency responsive optics for combining said first and second combined laser beams into a composite laser beam, said composite laser beam having substantially the same product of cross-sectional area and solid angle as each of said first and second combined beams.
16. A bright light source as defined in claim 15, wherein
said first plurality of semiconductor lasers are arranged in a first monolithic array; and
said second plurality of semiconductor lasers are arranged in a second monolithic array.
17. A bright light source as defined in claim 15 or 16 further including:
a third plurality of semiconductor lasers in which each of said third plurality of semiconductor lasers emits a beam of light of a third frequency;
a third bundle of optical fibers for receiving the light from ones of said third plurality of semiconductor lasers and providing a third combined laser beam of a predetermined shape and having a cross-sectional area and a solid angle.
18. The apparatus according to any one of claims 15 to 17, wherein
said semiconductor lasers are high power diode lasers.
19. The apparatus according to any one of claims 15 to 18, wherein
said frequency responsive optics include a dichroic combiner.

20. The apparatus according to any one of claims 15 to 18, wherein
said frequency responsive optics includes a grating.

21. The apparatus according to any one of claims 15 to 18, wherein
said frequency responsive optics include a holographic element.

22. The apparatus according to any one of claims 15 to 21, further including
a power detector for receiving a small fraction of the composite beam and for measuring the power of the
combined beam.

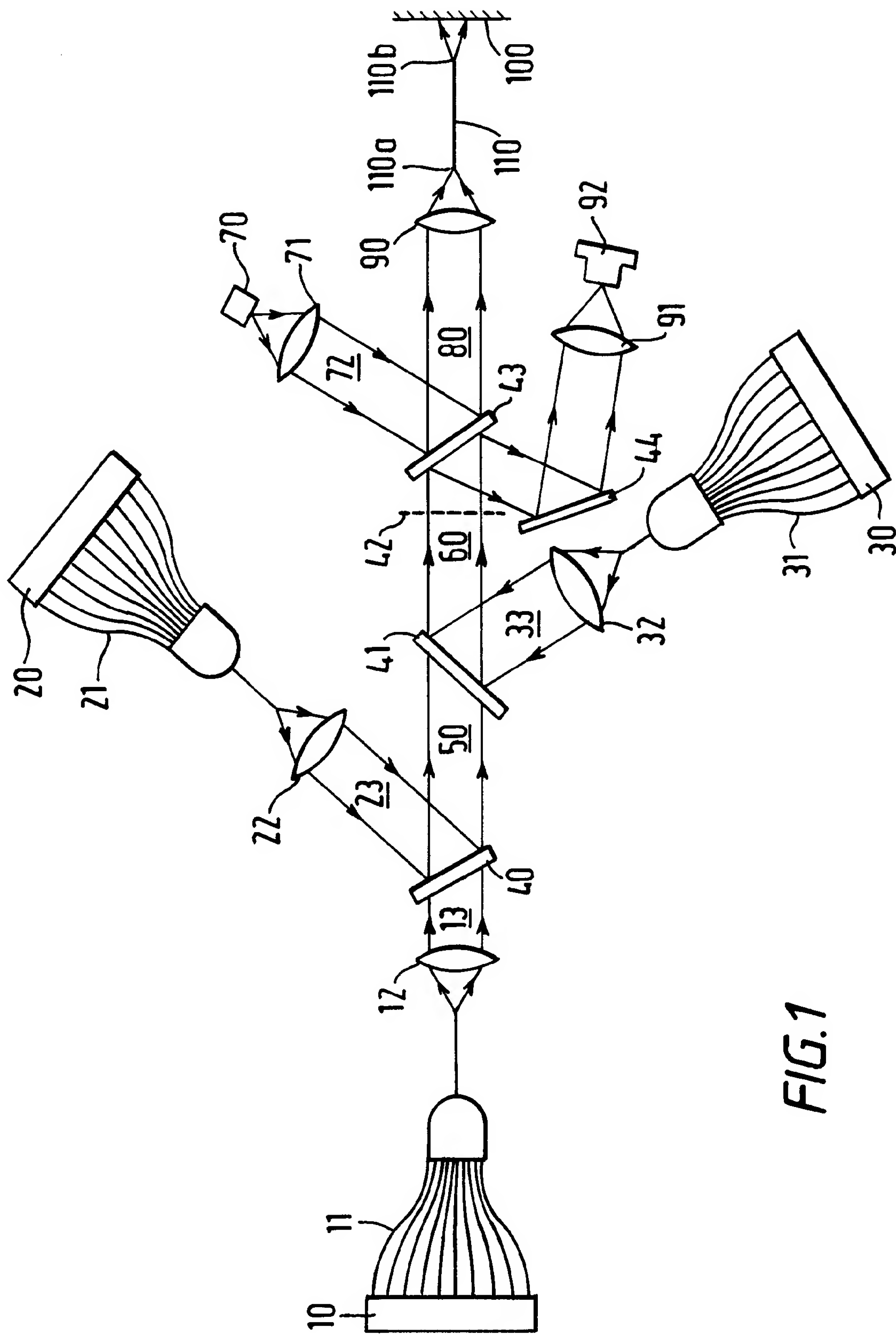
23. The apparatus according to any one of claims 15 to 22, wherein
each of said combined beams is at least 10 watts of power.

24. The apparatus according to any one of claims 15 to 23, wherein
said first plurality of semiconductor lasers each generates a laser beam of between 780 nm and 880 nm
inclusive; and
said second plurality of semiconductor lasers each generates a laser beam of between 920 nm and 940 nm
inclusive.

25. The apparatus according to any one of claims 15 to 24, including
a light source for generating an aiming beam of visible light and of a different wavelength than said plurality
of semiconductor lasers; and
a multiplexer for multiplexing said aiming beam into said combined laser beam.

26. The apparatus according to claim 25, wherein said further light source generates an aiming beam of 635 nm and
of a few milliwatts of power.

27. A light source comprising at least two semiconductor lasers effective to generate first and second laser beams of
different frequencies; and means for combining said second laser beams into a composite laser beam.





European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 94 30 7879

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	WO-A-93 21843 (COHERENT INC) * page 17, line 5 - page 18, line 17 * ---	1-6,9	H01S3/25 A61B17/36 G02B6/293
X	US-A-4 847 479 (G.L.CLARK) * figure 1 * ---	1,4,7-10	
Y	WO-A-91 12641 (SCIENTIFIC GENERICS LTD) * figure 3 * ---	15-21	
D	& GB-A-2 256 503 ---		
X	PATENT ABSTRACTS OF JAPAN vol. 6, no. 144 (E-122) (1022) 3 August 1982 & JP-A-57 068 098 (MITSUBISHI DENKI KK) 26 April 1982 * abstract * ---	1,4,14,27	
Y	* figures 1,2 * ---	15-21	
A	WO-A-91 01056 (AUSTRALIAN ELECTRO OPTICS PTY LTD) -----	15	
The present search report has been drawn up for all claims			TECHNICAL FIELDS SEARCHED (Int.Cl.6) H01S A61B G02B
Place of search THE HAGUE		Date of completion of the search 18 April 1995	Examiner Galanti, M
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

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Dental cleaning treatment laser device

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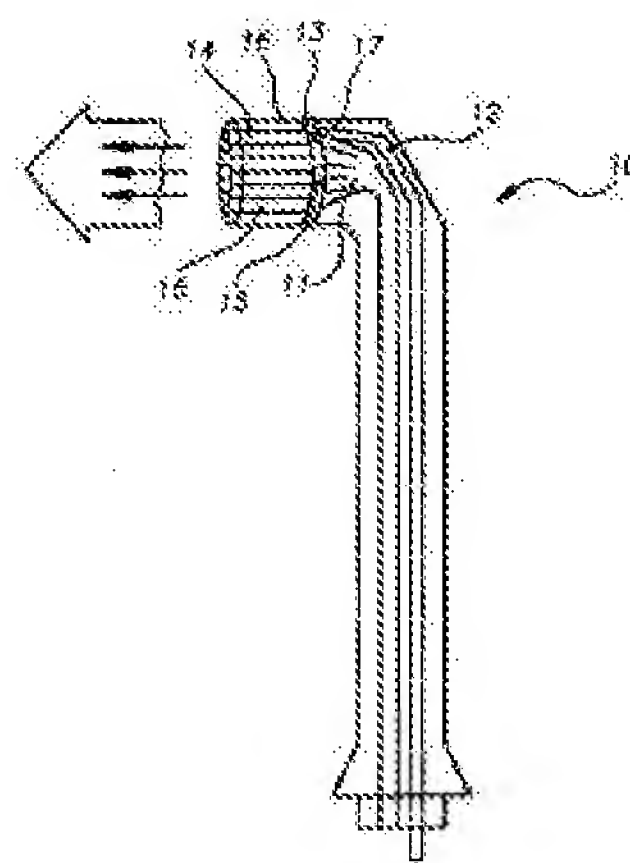
- EP0593375 (A1)
- WO9510243 (A1)
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- JP2136146 (A)

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Abstract of EP 0743029 (A2)

The invention is an oral cleaning device incorporating a low power laser radiation source and means for producing pulsed or continuous wave delivery of low power radiation to teeth, gums and oral tissue. The device is used alone or in conjunction with a liquid jet or jets and/or with photosensitizer dental paste or liquid. The device destroys bacteria and viruses in the mouth and on surrounding tissue. It increases oral blood circulation and enhances the body's immune system response to oral infection. The device may be operated by a trained professional at three different repetition rate frequencies, selected by the operator to treat different dental conditions. The specific photosensitizer liquid or paste which is activated at a certain wavelength is chosen by the operator to treat different dental conditions. The device is also intended for home dental hygiene at low power.

FIG. 1



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(54) Dental cleaning treatment laser device

Zahnärztliche Laservorrichtung zur Reinigungsbehandlung

Dispositif laser de nettoyage et de traitement dentaire

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- **PATENT ABSTRACTS OF JAPAN vol. 002, no. 135 (M-039), 10 November 1978 & JP 53 106254 A (MATSUSHITA ELECTRIC WORKS), 16 September 1978,**
- **J. PHOTOCHEM. PHOTOBIOLOG. B: BIOL., vol. 21, 1993, ELSEVIER, pages 81-86, XP000579457 VALDUGA ET AL.: "Effect of extracellularly generated singlet oxygen on Gram-positive and Gram-negative bacteria"**

● **PATENT ABSTRACTS OF JAPAN vol. 014, no. 370 (C-0747), 10 August 1990 & JP 02 136146 A (YOSHIDA DENTAL MFG CO LTD), 24 May 1990,**

- **PATENT ABSTRACTS OF JAPAN vol. 002, no. 135 (M-039), 10 November 1978 & JP 53 106254 A (MATSUSHITA ELECTRIC WORKS), 16 September 1978,**

- J. PHOTOCHEM. PHOTOBIO. B: BIOL., vol. 21, 1993, ELSEVIER, pages 81-86, XP000579457
VALDUGA ET AL.: "Effect of extracellularly generated singlet oxygen on Gram-positive and Gram-negative bacteria"

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EP 0 743 029 B1

Description

[0001] The invention relates generally to a tooth and mouth cleaning or treatment instrument and to a dental liquid or paste used in conjunction with the tooth and mouth cleaning or treatment instrument.

[0002] Generally in the prior art mechanical cleaning of teeth with manual, electric and/or water jet devices is of a superficial nature only and does not penetrate into the skin-tissue or into pockets to remove or destroy bacterial and viral contamination. Additionally, toothpaste is of very limited effect in terms of bacterial and viral destruction. Low power laser biostimulation produces enzymes which can destroy viruses and bacteria present on teeth, in the mouth, on the gums and below the gum line. Consequential inflammation and pain is also eliminated. Radiation with pulsed diode laser at varying repetition rate frequencies is a selective trigger of the body's natural defense to infection within the mouth. Optimum effect can be achieved with GaAs (Gallium Arsenide) pulsed diode laser at a width of 200-300 nsec, $\lambda = 904 \text{ nm}$, power = 5-10 mW, application time 1-3 minutes. Three different repetition rate frequencies can be used to treat different dental conditions as follows:

F1 = 73 Hz for Parodontitides, dental pain
F2 = 292 Hz for Gingivitis, stomatitis
F3 = 584 Hz for Gingivitis, stomatitis, paradontopathies

[0003] It is known through research in the area of photodynamid therapy that certain substances are created as a byproduct of laser radiation. These substances contain atomic or singlet oxygen that is believed to destroy tumor cells. Similarly, atomic oxygen resulting from laser radiation can enhance destruction of oral bacteria and viruses. Research has been conducted and reported which teaches that gram-positive and gram-negative bacteria are sensitive to singlet oxygen generated by a physically separated photosensitizer. Thus, laser radiation will destroy oral bacteria. [See, e.g., Giuliana Valduga *et al.*, "Effect of Extracellularly Generated Singlet Oxygen on Gram-positive and Gram-negative Bacteria," *J. Photochem. Photobiol. B. Biol.* 21 (1993) 81-86.]

[0004] The wavelength at which the diode laser of the device is operated is related to the specific photosensitizer used. A photosensitizer such as a Phthalocyanine can be activated by continuous wave diode laser as follows:

- (a) Zn(II) phthalocyanine is activated at $\lambda = 670 \text{ nm}$
- (b) Si(IV) naphthalocyanine is activated at $\lambda = 780 \text{ nm}$
- (c) Pd(OBu)₂ naphthalocyanine is activated at $\lambda = 820 \text{ nm}$

[0005] In EP-A-0593375, a dental appliance for brushing teeth is described. In it a laser beam is sent

down a central channel within the tooth brush until it hits one or more of semi-reflective elements and a final fully reflective element. The reflective elements are fixed within the head of the brush and use the principles of reflective optics to direct the laser beam parallel to the long axes of the bristles on the brush. The material of the head of the brush is a transparent plastic which allows the laser light to exit the head, after it is deflected, through spacing between bristles.

[0006] Once the laser is activated, its light is deflected by the reflective elements and exits the tooth brush. In some embodiments the laser beam travels through some plastic before striking the reflective elements and being deflected essentially perpendicular to its original traveling direction.

[0007] The present invention addresses the need for an oral cleaning or treatment device which will have a significant destructive effect on bacteria and viruses that will be reproducible over time, and which provides for safe, simple operation.

[0008] The objectives of the invention are as follows:

1. To provide a device to permit the delivery of low power radiation through a liquid jet or jets within the device.
2. To provide a device that permits the delivery of low power radiation directly from a low-power small radiator such as a diode-laser to areas of the oral areas to be treated or cleaned.
3. To provide a device that may be used separately from a cleaning device if desired, and that may provide variable treatment combinations by the selection of switches that control the radiation source, and that may provide sanitary, disposable treatment or cleaning portions of the device to allow multiple users to take advantage of the device.
4. To provide a cleaning material defined as a toothpaste or liquid to be used with the oral cleaning device which is radiation activated at certain wavelengths.
5. To respond to the need for an inexpensive, consumer-oriented hand-held tooth and mouth cleaning device which will emit low-power laser radiation for in-home treatment of oral infections, gingivitis and periodontal disease and for use by dentists and oral surgeons in preparation for surgery, in treatment of oral infection or during oral surgical procedures. Used in conjunction with the radiation activated toothpaste or liquid the effect on oral inflammation and infection is significant.

[0009] The present invention provides an oral cleaning device using low power radiation which enhances destruction of oral viruses and bacteria, increases blood circulation and thereby increases the body's immune system response to an oral infection. The present invention teaches a device which will have a significant effect on the treatment of all types of oral diseases, inflamma-

tions, and infections.

[0010] As an alternative to a pulsed diode laser, a continuous wave diode laser can be used with or without a photosensitizer liquid for selective biostimulation.

[0011] Low power laser radiation also increases blood circulation to maintain dental and gum health. The invention addresses these needs by teaching a consumer oriented device combining the benefits of mechanical cleaning with tissue penetration and virus/bacterial elimination using low power radiation delivered with either a pulsed or continuous wave mode.

[0012] The invention also teaches a photosensitizer dental liquid or paste to be used with the dental laser brush device which is activated by a laser wavelength. The photosensitizer toothpastes or liquid supplements increases the effectiveness of the laser assisted cleaning instrument.

[0013] The above, and other objects, features and advantages of the present invention will become apparent from the following description read in conjunction with the accompanying drawings.

[0014] Figure 1 is a view of the end of the mechanical oral cleaning device showing a circular fixed tip, optical fiber and liquid jet within the brushhead for laser radiation delivery, where the fiber optic's end terminates in at a safety-designed angle.

[0015] Figure 2 is a view of the end of a mechanical oral cleaning device of Figure 1 having a circular rotating tip.

[0016] Figure 3 is a sectional view of the mechanical oral cleaning device showing a brushhead, diode laser, power supply, cooling means and driver.

[0017] Figure 4 shows a mechanical oral cleaning device placed within a console having a colored, replaceable brush tips, means for a dental liquid dispenser and electrical components.

[0018] Figure 1 shows a preferred embodiment of the invention in which plastic brush 50 can be manufactured in a multiplicity of colors and is removable from a handle. Plastic brush 50 contains brushhead 56, optical fiber 51 and water or liquid passage 52. Optical fiber 51 carries radiation from a radiation source to fiber end 53, which terminates at designated angle 54 relative to optical fiber 51's longitudinal axis. Water or liquid passage 52 carries water or liquid under pressure to fiber end 53. Water or liquid passes through passage 52, over surface of fiber end 53, and then through liquid and laser radiation delivery opening 55 in brushhead 56 to any proximal oral area to be cleaned or treated. Plastic brush 50 is designed to be safe for home use by the fact that laser radiation coming to fiber end 53 will be reflected harmlessly upward into plastic brush 50 if no liquid is being forced through liquid passage 52. This is due to angle 54 which creates a reflective surface because air and optical fiber 51 have substantially different n. When liquid is passing over the surface of fiber end 53 laser radiation will pass through substantially parallel to the longitudinal axis of optical fiber 51, thereby being delivered

to oral areas to be cleaned or treated via opening 55 with the liquid that came through passage 52. This occurs because the difference in n between optical fiber 51 and a liquid or water is low enough that fiber end 53 is now a refractive, rather than a reflective, surface.

[0019] Figure 2 shows another preferred embodiment of the invention in which plastic brush 20 can be manufactured in a multiplicity of colors, is removable from a handle, and has rotatable brushhead 28. Plastic brush 20 contains optical fiber 21 and water or liquid passage 22. Optical fiber 21 carries radiation from a radiation source to fiber end 23, which terminates at designated angle 24 relative to optical fiber 21's longitudinal axis. Water or liquid passage 22 carries water or liquid under pressure to fiber end 23 just before rotatable brushhead 28. As described with reference to Figure 1, water or a liquid passes through passage 22, over surface of fiber end 23 and then through liquid and laser radiation delivery opening 25 to the oral areas being cleaned or treated. The rotating toothbrush bristles can facilitate cleaning or treatment in addition to the activity described earlier for the invention system.

[0020] Radiation is delivered by a pulsed diode laser or a continuous wave diode laser, to exactly where it is needed through plastic brush tips 50 or 20 in the normal course of tooth brushing. The present invention in these embodiments incorporates the properties of simple laser biostimulation which produces enzymes which remove and reduce the byproducts of tissue inflammation and thereby reduce swelling and assist to alleviate pain in the inflamed tissue.

[0021] Figure 3 shows handle means 31 containing diode laser 32 and electrical wiring 33, and cooling means 34 consisting of a Peltier cell. Radiation from diode laser 32 is delivered through replaceable brush 35. Handle means 31 may also contain battery cell or cells 36 which power diode laser 32.

[0022] Figure 4 shows the mechanical oral cleaning device placed within console 41 whereby the handle means 42 enclosing a diode laser is secured and replacement brushes 43 are easily accessible. Console 41 also contains container 44 for storage of the dental or photosensitizer liquid or paste. Console 41 contains within its structure a sufficient length of cable for use of the brushing device in dental surgery or for any other application. Console 41 also contains within its structure a micropump for any liquid under pressure that may be needed and all needed electrical circuits.

[0023] In the present invention, the dental laser brushing device can be used in combination with a photosensitizer toothpaste or liquid which is applied to the bristles of the device. The photosensitizer liquid or paste when activated by an appropriate laser wavelength produces hyperactive singlet oxygen that destroys bacteria. The method is similar to photodynamic therapy of tumors in which the photosensitizer releases singlet oxygen that destroys tumor cells. The present invention uses low power laser energy delivered by pulsed or by continuous

wave! action! and! a! low! concentration! of! photosensitizer for! consumer! use! The! dental! laser! brushing! device! may be! used! in! connection! with! oral! surgery! at! a! medium! laser! energy! delivery! and! using! a! specific! concentration of! photosensitizer! liquid! The! present! invention! guarantees! good! penetration! of! oral! tissues.

[0024] The! low! power! radiation! can! be! delivered! at three! (3)! different! frequencies! which! can! be! selected! by the! operator! based! upon! the! particular! treatment! to! be rendered! and! the! particular! photosensitizer! liquid! used. The! result! is! photodynamic! therapy! whereby! the! selection! of! diode! laser! wavelength! is! related! to! the! type! of treatment! to! be! conducted.

[0025] In! a! preferred! embodiment! of! the! invention! and as! shown! in! the! drawings,! the! diode! laser! can! be! incorporated! into! the! handle! of! the! device! together! with! its power! supply! and! if! necessary,! with! Peltier! cells! as! a cooling! system! Radiation! from! a! diode! laser! source! is delivered! through! one! or! more! of! the! bristles! on! a! replaceable! brush! that! has! a! fixed! or! rotatable! brushhead, or! through! liquid! jets,! or! through! openings! in! the! brushhead! corresponding! to! the! radiation! delivery! medium The! diode! laser! will! run! on! the! battery! or! battery! cells inside! the! handle! The! replaceable! brushes! have! one! of two! types! of! brushheads:

- (a) rotating! bristles! which! are! activated! by! applying the! bristles! to! the! oral! surface! or! by! the! pressure! of the! flow! of! liquid! through! the! jets;
- (b) fixed! bristles! which! are! activated! by! applying! the bristles! to! the! oral! surface! or! by! the! pressure! of! the flow! of! liquid! through! the! liquid! jets.

[0026] The! rotating! motion! of! the! bristles,! the! pulsing action! of! the! pulsed! delivery,! and/or! the! pressure! of! the liquid! jets! all! increase! the! effectiveness! of! the! device.

[0027] Also! in! a! preferred! embodiment! of! the! invention,! the! handle! containing! the! diode! laser! is! linked! to! a console! by! cable! where! there! are! electrical! wires! and small! tubing! for! delivery! of! the! dental! liquid! The! console contains! all! the! necessary! electronic! components! for operation! of! the! dental! laser! brushing! device! The! console! contains! a! container! to! hold! the! dental! liquid! or paste! and! its! micropump! This! dental! liquid! can! be! a toothpaste,! a! pharmacological! substance! for! medical treatment! and/or! a! photosensitizer! liquid! for! photodynamic-like! therapy.

[0028] Various! replacement! brushes! can! be! inserted into! the! handle! with! an! easy! snap! connection! that! guarantees! optical! connection! between! the! diode! laser! and the! optical! fiber! in! the! brush,! and! between! the! tubing that! delivers! the! dental! liquid! to! the! tubing! in! the! brush. The! brushes! may! be! different! colors! for! easy! individual identification! by! multiple! users! within! a! family! The brushes! may! also! be! sterilized! for! professional! use! by dentists! and! oral! surgeons.

[0029] Having! described! the! preferred! embodiment! of the! invention! with! references! to! the! accompanying

drawings,! it! is! to! be! understood! that! beyond! the! precise description! above! the! invention! includes! changes! and modifications! effected! therein! by! one! skilled! in! the! art which! do! not! depart! from! the! invention! as! defined! in! the appended! claims.

Claims

1. A! dental! cleaning! or! treatment! device! having! a! handle,! a! brushhead! (56)! comprising! a! backing! plate and! a! multiplicity! of! bristles,! a! radiation! source,! a power! source! for! the! radiation! source,! and,! a! means for! delivery! of! the! radiation! from! the! source! to! the free! end! of! the! bristles,! which! is **characterized! by:**

the! delivery! means! for! the! radiation! comprising an! optical! fiber! (51,! 21)! optically! connected! to the! radiation! source;
the! optical! fiber! (51,! 21)! terminating! such! that the! optical! fiber's! longitudinal! axis! is! substantially! directed! at! an! opening! (55,! 25)! in! the brushhead! (56);
the! opening! (55,! 25)! allowing! passage! of! liquid and! radiation! to! oral! areas! to! be! cleaned;
a! tube! (52,! 22)! providing! passage! for! liquid! under! pressure;
the! optical! fiber! (51,! 21)! has! a! termination-tip (53,! 23)! which! forms! a! substantially! flat! surface relative! to! the! optical! fiber's! longitudinal! axis;
the! tube! (52,! 22)! has! an! open-end! substantially near! the! termination-tip! (53,! 23);
a! liquid! coming! through! the! open-end! passes over! the! surface! of! the! termination-tip! (53,! 23);
an! angle! formed! between! the! surface! of! the! termination! tip! (53,! 23)! and! the! optical! fiber's! longitudinal! axis! forms! a! substantially! refractive surface! for! the! radiation! while! liquid! is! passing over! the! surface! and! then! to! the! opening! thereby! passing! the! radiation! substantially! through the! opening! (55,! 25);
the! angle! forming! a! substantially! reflective! surface! for! the! radiation! when! the! liquid! is! not passing! over! the! surface,! thereby! passing! the radiation! substantially! to! the! brushhead! (56).

2. A! dental! device! of! claim! 1! further **characterized! by:**

the! radiation! source! being! a! diode-laser! either enclosed! in! the! handle! (31)! or! in! a! separate! enclosure! and! connected! to! the! handle! (31)! by! an optically! conductive! means.

3. A! dental! device! of! claims! 1! or! 2! further **characterized! by:**

the! device! having! at! least! a! brushhead! (56) which! is! considered! disposable.

4. A dental device of claims 1, 2 or 3 further **characterized by**: the brushhead (56) and the handle being substantially rigidly connected by an attachment means such that the brushhead may be used to apply needed pressure to oral areas, and where the attachment means allows brushheads to be changed. 5
5. A dental device of claim 4 further **characterized by**: the brushhead backing plate and the multiplicity of bristles being connected by a rotating means (28), allowing said bristles to move relative to said backing plate. 10 15
6. A dental device of claims 1, 2, 3, 4, or 5 further **characterized by**: having means to deliver and select different radiation frequencies for treatment of a particular oral infection or condition. 20
7. A dental device of claims 1, 2, 3, 4, 5, or 6 further **characterized by**: having a means to deliver and select laser radiation in a pulsed mode or in a continuous wave mode. 25 30
8. A method of using the dental cleaning or treatment device according to any of claims 1-7 wherein a dental liquid or paste containing photosensitizer substances is used with the dental device, which can activate the photosensitizer substance, on an oral area covered with the liquid or paste. 35
9. A method according to claim 8 of using the dental cleaning or treatment device wherein either concurrently or after application of the photosensitizer substance to oral areas the substance is activated by exposure to the radiation source of the device. 40

Patentansprüche

1. Eine zahnmedizinische Reinigungs- oder Behandlungsvorrichtung mit einem Griff, einem Bürstenkopf (56) mit einer Grundplatte und einer Vielzahl von Borsten, einer Strahlungsquelle, einer Stromquelle für die Strahlungsquelle, und einem Mittel zur Zuführung der Strahlung von der Strahlungsquelle zum freien Ende der Borsten, **dadurch gekennzeichnet, dass**: das Mittel zur Zuführung für die Strahlung eine optische Faser (51, 21) umfasst, die optisch mit 50 55

der Strahlungsquelle verbunden ist; die optische Faser (51, 21) am Ende so abgeschlossen ist, dass die Längsachse der optischen Faser im wesentlichen auf eine Öffnung (55, 25) in dem Bürstenkopf (56) gerichtet ist; die Öffnung (55, 25) den Durchtritt von Flüssigkeit und Strahlung in zu reinigenden Mundbereiche erlaubt; ein Röhrchen (52, 22) den Durchfluss von unter Druck befindlicher Flüssigkeit ermöglicht; die optische Faser (51, 21) eine Abschluss-Spitze (53, 23) besitzt, die bezogen auf die Längsachse der optischen Faser, eine im wesentlichen flache Oberfläche bildet; das Röhrchen (52, 22) im wesentlichen im Bereich der Abschluss-Spitze (53, 23) ein offenes Ende aufweist; eine Flüssigkeit, die aus dem offenen Ende austritt, über die Oberfläche der Abschluss-Spitze (53, 23) fließt; ein Winkel zwischen der Oberfläche der Abschluss-Spitze (53, 23) und der Längsachse der optischen Faser im wesentlichen eine Brechungsfläche für die Strahlung bildet, während Flüssigkeit über die Oberfläche und dann zu der Öffnung fließt, wodurch die Strahlung im wesentlichen durch die Öffnung (55, 25) geführt wird; der Winkel im wesentlichen eine reflektierende Fläche für die Strahlung bildet, wenn die FIOsigkeit nicht über die Oberfläche läuft, wodurch die Strahlung im wesentlichen in den Bürstenkopf (56) geführt wird.

2. Eine zahnmedizinische Vorrichtung nach Anspruch 1, weiter **dadurch gekennzeichnet, dass**:

die Strahlungsquelle ein Diodenlaser ist, der sich entweder in dem Griff (31) oder in einem getrennten Gehäuse befindet und mit dem Griff (31) über ein optisch leitendes Mittel verbunden ist.

3. Eine zahnmedizinische Vorrichtung nach Anspruch 1 oder 2, weiter **dadurch gekennzeichnet, dass**:

die Vorrichtung mindestens einen Bürstenkopf (56) hat, der als Einwegartikel betrachtet wird.

4. Eine zahnmedizinische Vorrichtung nach Anspruch 1, 2 oder 3, weiter **dadurch gekennzeichnet, dass**:

der Bürstenkopf (56) und der Griff im wesentlichen starr über eine Halterung miteinander verbunden sind, so dass über den Bürstenkopf der notwendige Druck auf die betreffenden Mundbereiche ausgeübt werden kann und wobei die

Halterung! ein! Auswechseln! des! B!Orstenkopfes erlaubt.

5. Eine! zahnmedizinische! Vorrichtung! nach! Anspruch 4,! weiter **dadurch! gekennzeichnet,! dass:**

die Grundplatte! des! Bürstenkopfes! and! die Vielzahl! der! Borsten! Ober! eine! drehbare! Vorrichtung! (28)! miteinander! verbunden! sind,! die eine! Bewegung! der! genannten! Borsten! in! Bezug! zu! der! genannten! Grundplatte! ermöglicht.

6. Eine! zahnmedizinische! Vorrichtung! nach! Anspruch 1,! 2,! 3,! 4! oder! 5,! weiter **dadurch! gekennzeichnet, dass:**

sie! Mittel! zur! Zuführung! and! Auswahl! verschiedener! Strahlungsfrequenzen! zur! Behandlung einer! bestimmten! Infektion! oder! eines! bestimmten! Zustandes! im! Mund! aufweist.

7. Eine! zahnmedizinische! Vorrichtung! nach! Anspruch 1,! 2, **3,! 4,! 5** oder! 6,! weiter **gekennzeichnet! dadurch,! dass:**

sie! ein! Mittel! zur! Zuführung! and! Auswahl! von Laserstrahlung! im! Impulsbetrieb! (pulsed! mode)! oder! im! Dauerbetrieb! (continuous! wave mode)! aufweist.

8. Eine! Methode! zur! Verwendung! der! zahnmedizinischen! Reinigungs-! oder! Behandlungsvorrichtung nach! einem! der! Ansprüche! 1! bis! 7,! bei! der! eine zahnmedizinische! Flüssigkeit! oder! Paste,! die! Photosensibilisatorsubstanzen! enthält,! in! Verbindung mit! der! zahnmedizinischen! Vorrichtung! verwendet wird, welche! die! Photosensibilisatorsubstanz! auf einem! Mundbereich,! der! mit! der! Flüssigkeit! oder Paste! bedeckt! ist,! aktivieren! kann.

9. Eine! Methode! nach! Anspruch! 8! zur! Verwendung der! zahnmedizinischen! Reinigungs-! oder! Behandlungsvorrichtung,! bei! der! entweder! gleichzeitig oder! nach! Aufbringung! der! Photosensibilisatorsubstanz! auf! die! Mundbereiche! die! Substanz! aktiviert wird,! indem! man! sie! der! Strahlungsquelle! der! Vorrichtung! aussetzt.

Revendications

1. Un! dispositif! de! nettoyage! ou! de! traitement! dentaire doté! d'une! poignée,! d'une! tête! de! brosse! (56)! comprenant! une! plaque! de! support! et! une! variété! de brosses,! d'une! source! de! rayonnement,! d'une! source! de! courant! pour! la! source! de! rayonnement! et d'un! moyen! pour! le! transport! du! rayonnement! de! la source! à! l'extrémité! libre! des! brosses,! qui! est **ca-**

racterise! par! :

le moyen! de! transport! du! rayonnement! qui comprend! une! fibre! optique! (51,! 21)! dotée d'une! connexion! optique! avec! la! source! de rayonnement!;

la! fibre! optique! (51,! 21)! qui! se! termine! de! telle manière! que! ('axe! longitudinale! de! la! fibre! optique! est! substantiellement! dirigé! vers! une ouverture! (55,! 25)! dans! la! tête! de! brosse! (56)!; ('ouverture! (55,! 25)! qui! permet! le! passage! du liquide! et! du! rayonnement! vers! les! zones! buccales! à! nettoyer!;

un! tube! (52,! 22)! permettant! le! passage! de! liquide! sous! pression!;

la! fibre! optique! (51,! 21)! à! une! extrémité! (53,! 23)! qui! forme! une! surface! substantiellement! plate! par! rapport! à! ('axe! longitudinale! de! la! fibre! optique!;

le! tube! (52,! 22)! à! une! extrémité! ouverte! substantiellement! proche! de! l'extrémité! (53,! 23)!;

un! liquide! qui! traverse! l'extrémité! ouverte! passe! sur! la! surface! de! l'extrémité! distale! (53,! 23)!;

un! angle! forme! entre! la! surface! de! l'extrémité (53,! 23)! et! ('axe! longitudinale! de! la! fibre! optique

forme! une! surface! de! refraction! substantielle pour! le! rayonnement! alors! que! le! liquide! passe sur! la! surface! puis! vers! ('ouverture,! faisant! alors passer! substantiellement! le! rayonnement! à! travers! ('ouverture! (55,! 25)!;

('angle! qui! forme! une! surface! de! réflexion! substantielle! pour! la! radiation! quand! le! liquide! ne passe! pas! sur! la! surface,! et! qui! fait! alors! passer le! rayonnement! vers! la! tête! de! brosse! de! manière! substantielle! (56).

2. Un! dispositif! dentaire! conforme! à! la! revendication 1! en! outre **caractérise! par! :**

la! source! de! rayonnement,! qui! est! un! laser! à diode! logé! soit! dans! la! poignée! (31),! soit! dans un! logement! séparé! et! relié! à! la! poignée! (31) par! un! moyen! de! conduction! optique.

3. Un! dispositif! dentaire! conforme! aux! revendications 1! ou! 2! en! outre **caractérise! par**

le! dispositif! qui! a! au! moins! une! tête! de! brosse (56)! considérée! comme! jetable.

4. Un! dispositif! dentaire! conforme! aux! revendications 1,! 2! ou! 3! en! outre **caractérise! par:**

la! tête! de! brosse! (56)! et! la! poignée,! qui! sont substantiellement! connectées! de! manière! rigide! par! un! moyen! de! fixation! qui! permet! d'utiliser la! tête! de! brosse! pour! appliquer! la! pression! nécessaire! aux! zones! buccales,! le! moyen! de! fixation!

tion! permettant! de! changer! la! tête! de! brosse.

5. Un! dispositif! dentaire! conforme! à! la! revendication 4! en! outre **caractérise! par!**:

5

la! plaque! de! support! de! la! tête! de! brosse! et! la variété! de! brosses! connectées! par! un! moyen rotatif! (28),! qui! permettent! aux! dites! brosses! de bouger! par! rapport! à! la! dite! plaque! de! support.

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6. Un! dispositif! dentaire! conforme! aux! revendications 1,!2,!3,!4! ou! 5! en! outre **caractérise! par!**:

la! présence! de! moyens! de! transport! et! de! sélection! de! différentes! fréquences! de! rayonnement! pour! le! traitement! d'une! infection! ou! d'un & tat! buccal! particuliers.

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7. Un! dispositif! dentaire! conforme! aux! revendications 1,!2,!3,!4,!5! ou! 6! en! outre **caractérise! par!**:

20

la! présence! d'un! moyen! de! transport! et! de! sélection! de! rayonnement! laser! en! mode! pulse! ou en! mode! de! guide! d'ondes! continu.

25

8. Une! méthode! qui! utilise! le! dispositif! de! nettoyage ou! de! traitement! dentaire! conformément! à! chacune des! revendications! 1! à! 7,! dans! laquelle! un! liquide ou! une! pâte! dentaire! contenant! des! substances photosensibles! sont! utilisés! avec! le! dispositif! dentaire,! qui! peut! activer! la! substance! photosensible sur! une! zone! buccale! couverte! du! liquide! ou! de! la pâte.

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9. Une! méthode! conforme! à! la! revendication! 8! d'utilisation! du! dispositif! de! nettoyage! ou! de! traitement dentaire,! dans! laquelle! la! substance! photosensible est! activée! par! exposition! à! la! source! de! rayonnement! du! dispositif! pendant! ou! après! l'application! de cette! dernière! sur! les! zones! buccales.

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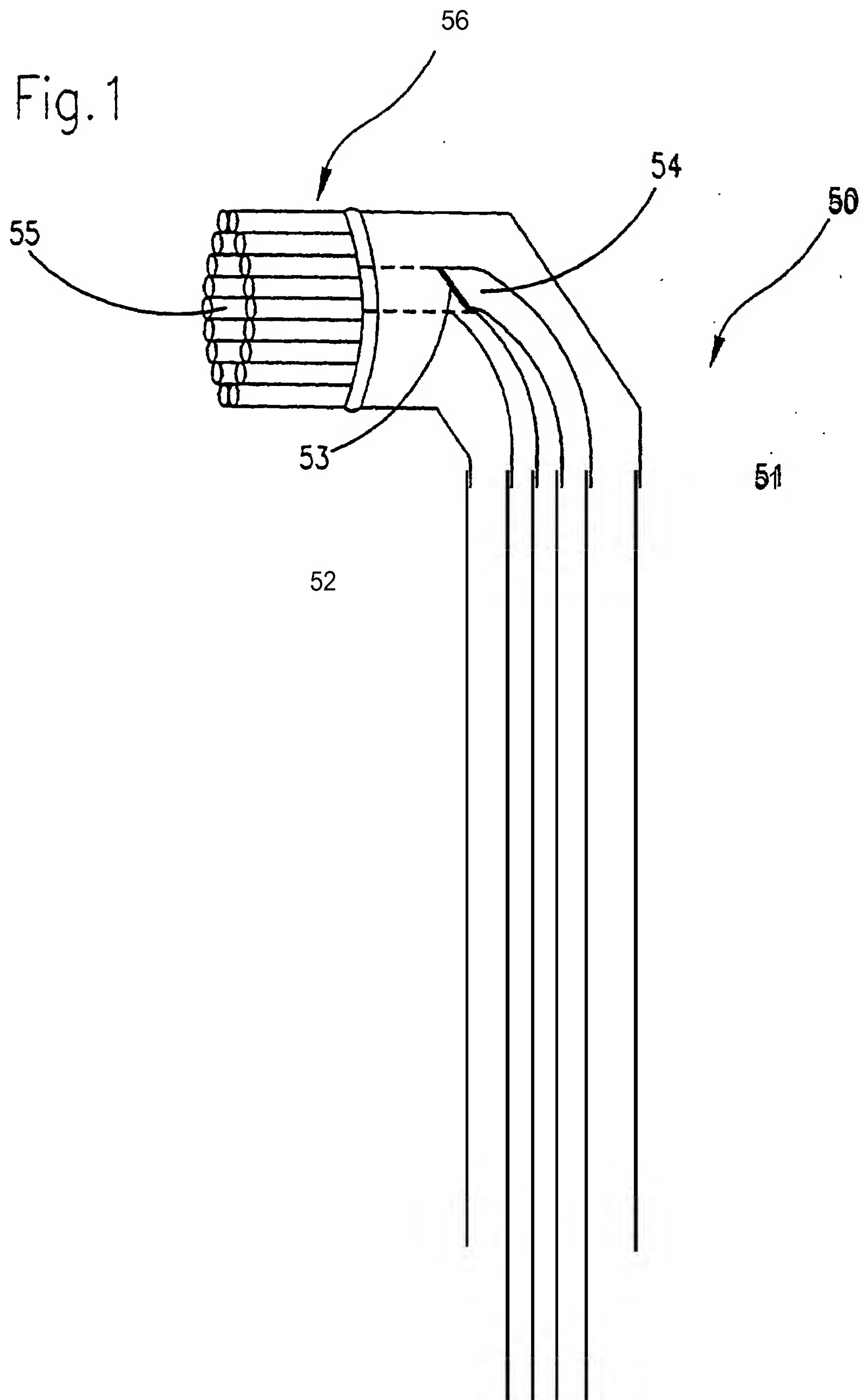


Fig.2

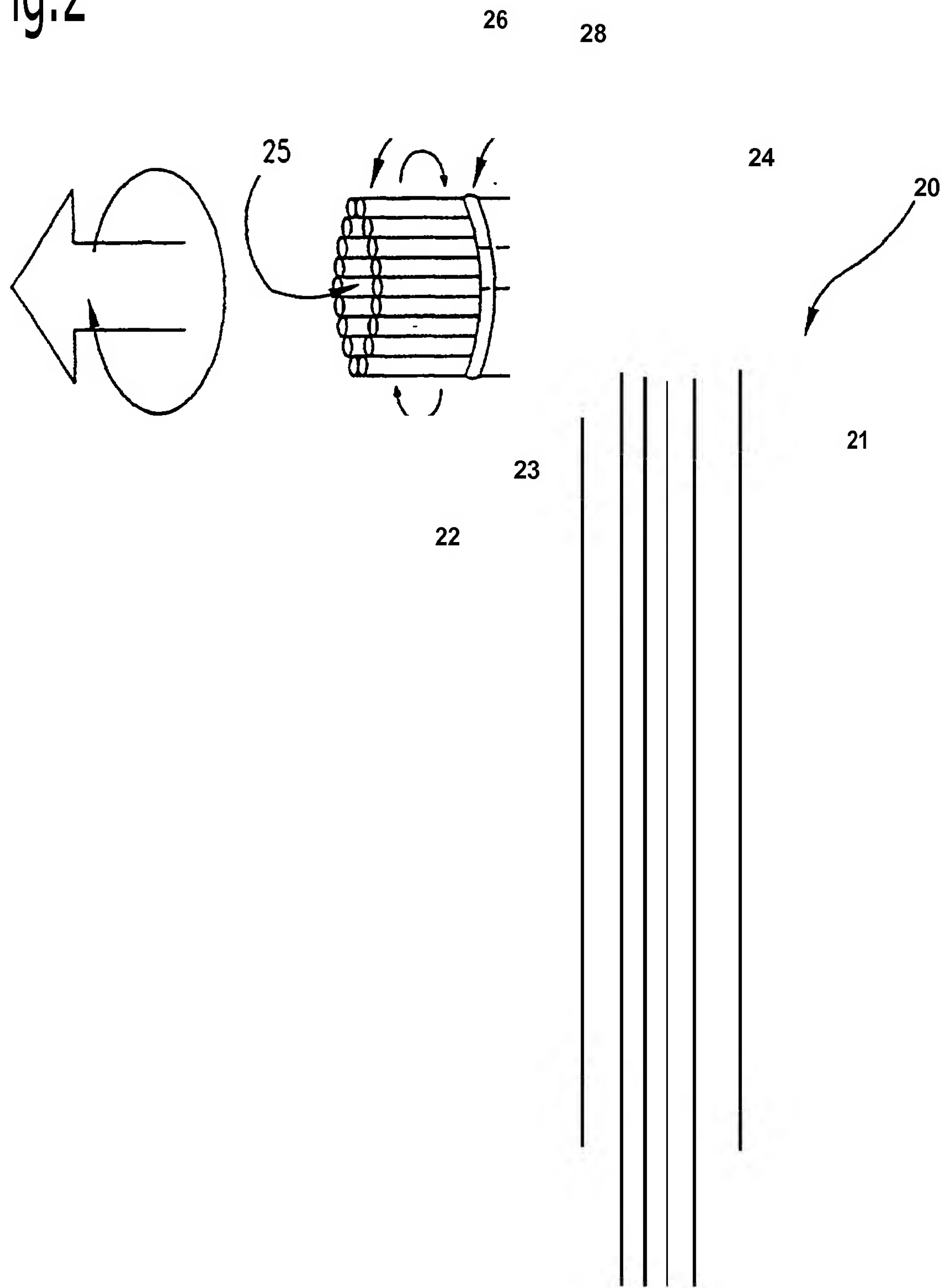
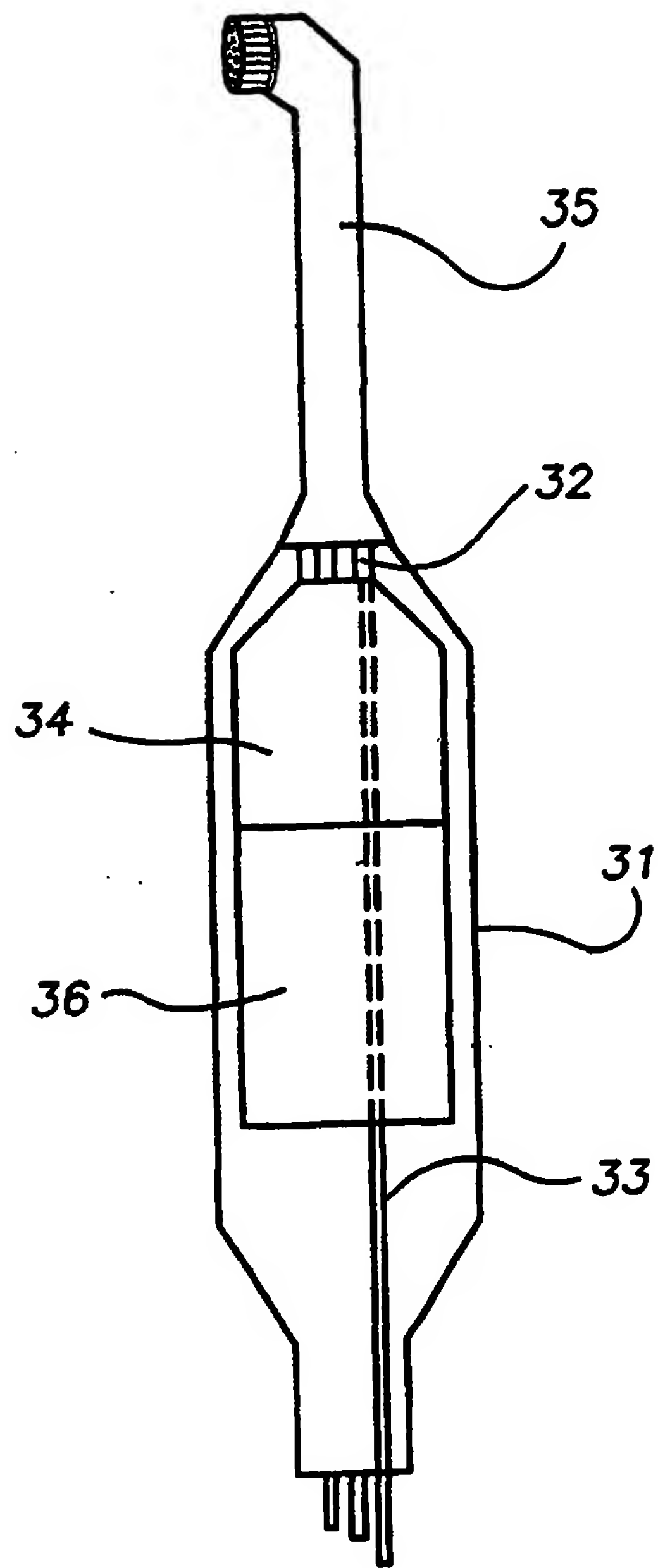
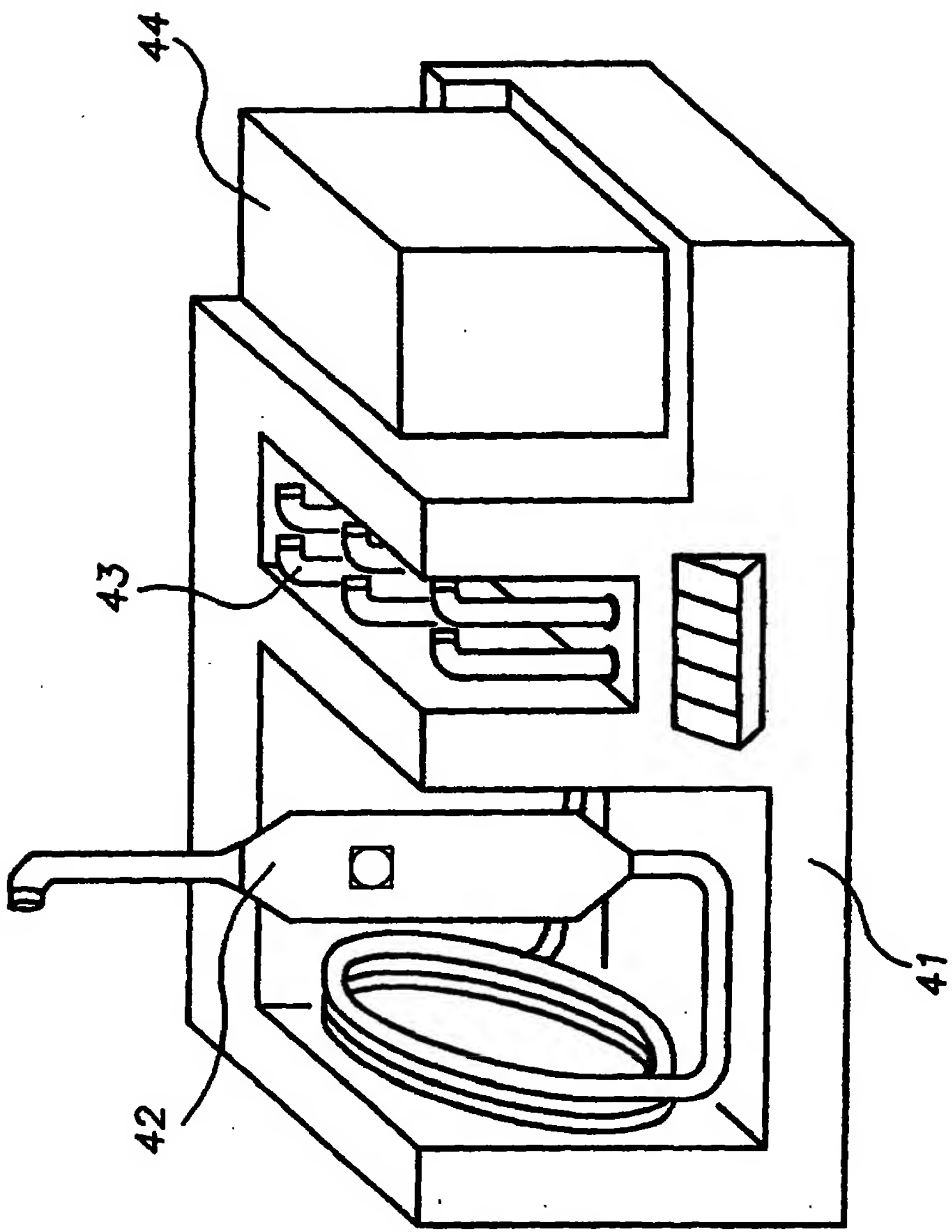
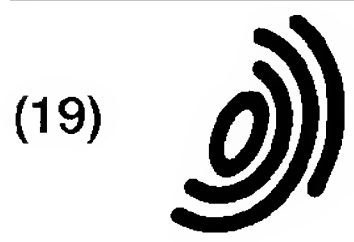


FIG.3



FIG





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Remarks:

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under INID code 62.

(54) **Small-sized light irradiator for dental use**

(57) A small-sized light irradiator for dental use
comprises

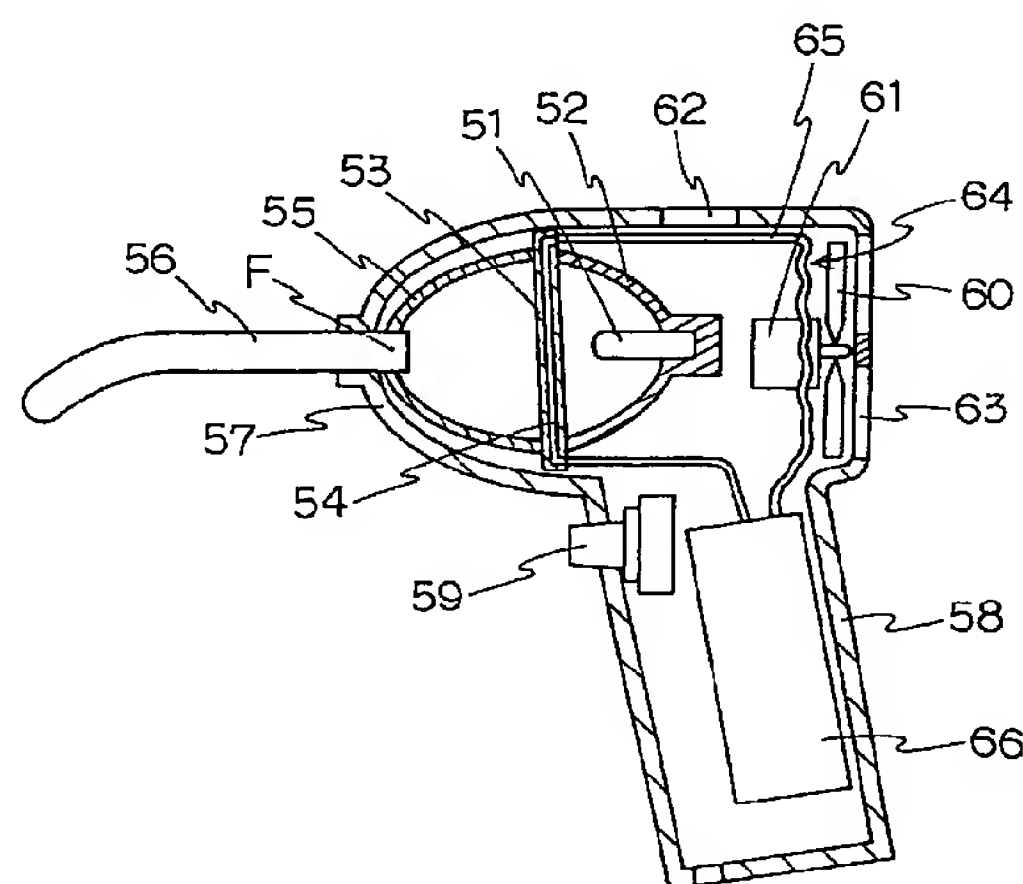
(a) a light source (51) emitting visible, infrared and
ultraviolet light and provided with a substantially
half-ball shaped reflector (52) which converges at
least visible light of said three kinds of light to a pre-
determined direction;

(b) a transparent cell (53, 91) transmissive to visible
light, disposed on the emission side of said light
source (51) to absorb infrared and ultraviolet light,
and having a hollow space therein charged with liq-
uid coolant;

(c) a light guide (56) disposed such that light pass-
ing through said cell (53) impinges on its one side
end and emits from its other side which is directed
to a predetermined direction; and

(d) a casing (57) with a handle (58) enclosing said
light source (51) and transparent cell (53, 91) and
provided with said light guide (56) to its one end.

FIG. 1



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Description

[0001] The present invention relates to a small-sized light irradiator for dental use according to the preamble of claim 1, which is used for curing composite resin or curing the inlay within mouth in the dental cure.

[0002] A small-sized light irradiator of this type is known from US 4 623 795 A.

[0003] In the dental curing, it is known that such a method for curing the photopolymerizing resin such as composit resin, which is charged in the dental caries, by irradiation. In such a curing, a small-sized light irradiator has hitherto been used, and known (for example Japanese Examined Utility Model Publication No. 36491/1990).

[0004] In many cases, a halogen lamp is used as a light source of the light irradiator. The halogen lamp outputs visible light, the amount of which is much enough to be suitable for the light source of the light irradiation. However, infrared lights are excessively emitted so as to heat the lamps and neighborhood thereof too much. Conventionally, a filter for the infrared lights is disposed in the output side of the light source and an exhaust fan is disposed in the back side of the light source so that the lamp and the whole device are cooled using the air cooling method. However, such a construction is insufficient for cooling. Therefore, such a halogen lamp as to perform practically cooling effect at low power can be used. It is impossible to cure an inlay in the mouth by photopolymerizing. Further, lights emitted from the halogen lamp includes ultraviolet lights so that there arises such a problem as to cause a suffering due to direct irradiation to the structure of the mouth.

[0005] In the irradiator according to US 4 623 795 A, the light source, reflector and transparent cell are disposed inside the casing in such a manner that a pressurised cooling gas may pass between the inner surface of the casing and the outside of the reflector and transparent cell.

[0006] The object of the present invention is to resolve the above-mentioned problems.

[0007] This object is achieved by a small-sized light irradiator for dental use according to claim 1.

[0008] Advantageous embodiments of the invention are described in the subclaims.

[0009] It is preferred that said transparent cell of visible light is connected to a pump and a heat exchanger via a tube so as to circulate said liquid coolant.

[0010] It is preferred that said transparent cell is composed of a disc-like shaped cell main body having a hollow space therein, and two fine tubes for fluid circulation fixed to said cell main body to communicate with said hollow space.

[0011] Alternatively, said transmission cell of visible light is composed of a conical shaped cell main body having a hollow space therein and two fine tubes for fluid circulation fixed to said cell main body to communicate with said hollow space, wherein said conical

shaped cell is disposed such that a bottom portion of said conical shaped cell is faced to the light source, a tip of said conical shaped cell is faced to a side of one of said light guide.

[0012] It is further preferred that said transparent cell is integrally formed so as to be combined with said reflector, and wherein said reflector has a duplex structure such that a space for communicating with the hollow space within said transparent cell is formed in the reflector.

[0013] It is preferred that a part of said tubes are wound so as to be in contact with an outside surface of said reflector, and wherein said tubes are made of such a metal pipe as to have a good heat conductivity capable of absorbing heat of said reflector.

[0014] It is preferred that said pump and said heat exchanger are accommodated in said casing.

[0015] Alternatively, said pump and said exchanger are arranged in such a manner as to be separated from said casing.

[0016] In the following, preferred embodiments of the invention are described in detail with respect to the accompanying drawings.

FIG. 1 is a sectional view showing one embodiment of the small-sized light irradiator of the present invention;

Fig. 2 is a perspective view showing a transparent cell attached to the light irradiator of Fig. 1;

Fig. 3 is a sectional view taken along with a line III-III in Fig. 2;

Fig. 4 is a sectional view showing another embodiment of the present invention;

Fig. 5 is a partial sectional view showing relevant part in Fig. 4;

Fig. 6 is a sectional view showing an embodiment of the use of the present invention; and

Fig. 7 is a sectional view showing an embodiment of the use of the present invention.

[0017] Fig. 1 shows a small-sized light irradiator, herein numeral 51 indicates light source, for example, halogen lamp emitting visible, infrared and ultraviolet lights. As a light source, xenon lamp, metalhalide lamp and the like can be used other than halogen lamp. Numeral 52 indicates substantially half-ball shaped reflector wherein said halogen lamp and reflect visible light. Numeral 53 indicates transparent cell of visible light which is disposed open space of the reflector 52 i.e. the emission side of the light, charged fluid 54 therein. This all functions as a filter of infrared light absorbent and ultraviolet light. Namely, more than about 80 % of the infrared light and almost all of the ultraviolet light contained in impinging to said cell 53 is absorbed. Numeral 55 indicates another reflector which is disposed outside of the cell 53. Water, ethyleneglycol or silicone oil can be used as fluid 54.

[0018] Numeral 56 indicates light guide formed of

glass fiber, the visible light which transmit the cell 53 impinge from one side thereof, further emit from other side end which is directed to a desired direction. Casing is rotatably provided with light guide 56, and light guide 56 is detachably inserted into the casing. Casing 57 is formed of plastics which is disposed a handle 58. Numeral 59 indicates a power switch which is equipped to the handle 58. Numeral 60 indicates disclosed fan for air exhaust, which is driven by motor 61. Driving fan 60 supplies air from hole 62 for air supply, further evacuate air through hole air exhaust. Adjacent to the fan 60, heat-exchanger 64 which is subjected to blowing air from folded tube 65. Tube 65 is communicated between cell 53 and a pump 66. This pump 66 can be of the construction having a tank for water storage therein (not shown in the figure). With such a construction, fluid 54 charged in the cell 53 is circulated by the pump 66, and cooled at heat exchanger 64. Namely, heated fluid 54 by absorbence of infrared light at the cell 53 is cooled at heat exchanger 64, and again supplied to cell 53. Motor 61 can change its ON-OFF State by operation of power switch 59. Lamp 51, motor 61, pump 66 and power switch 59 are connected by a electronic code which is not shown in the Figure. One motor can be used both as motor 61 and motor for driving of pumps 66. Tubing at the heat exchanger 64 is preferably formed with metal pipe which is superior to heat conductivity such as copper pipe, and at the other portion of tubing elastic silicone tube can be used.

[0019] As shown in Fig. 2 and 3, transparent cell is composed of two transplant glasses 67, 68 which are spaced with a space 69 in 3 mm thickness between them, and fluid 54 is charged to the space 69. Two glasses 67, 68 can be spaced with adhesive 70, to seal space 69. Numeral 71 indicates fine tubes with which communicating space 69, and one of them are used as supply and the other as drain of water. This transparent cell 53 can be composed of heat resistant plastic or heat resistant glass. Two glasses 67, 68 of transparent cell 53 can be also be constructed to concave lens by changing their thickness adequately. Emission light from lamp 51 concave to the spot F, which is indside of the light guide 56 directly, or by reflection at reflector 52 and by further transmission through transparent cell 53.

[0020] Fig. 4 shows another embodiment of the present invention comprising of integrally formed cone-shaped cell main body 78 having vacant space therein by heat resistant glass and two fine tubes 79, 79 for fluid circulation which are communicated with said vacant space thereby fixed to said cell main body 78. In a vacant space of inside of the cell main body 78, aforementioned fluid 54 is charged, Inner surface of the vacant space of cell main body 78 is provided with mirror 90 to reflect light.

[0021] Down-side of the cone of cell main body 78, faces to open end of reflector 52, top of the cone faces to one edge of light guide 56. The light emitted from light source 51 therefore impinge on transparent cell 91, lim-

ited almost of infrared light and ultraviolet light by fluid 54 therein, converge to spot F inside of light guide 56 while reflecting to mirror 90, further is introduced by light guide 56. Light impringed to light guide 56 which comprises visible light mainly, is emitted from another side of the guide.

[0022] Numeral 80 indicates tubular member which is wound on the spherical surface of the reflector 52 in such a manner as to be closely connected each other thereon, made of metal pipe having superior heat conductivity such as copper, one side being connected to fine tube 79 and the other to silicone tube 65, thereby introduced out side of casing 57. As shown in Fig. 5, numeral 81 indicates heat conductive filling plugged to space between metal pipe of cooler 80 and reflector 52 which can be used the solidified powder of alminium with epoxy resin or silicon resin. Numeral 82 indicates heat exchanger disposed to out side of the casing 57, comprising pump 83, metal pipe 84 having excellent heat conductivity which is coiled to spiral form and fan 85. Pump 83 and metal pipe are connected to tube 65 serially. From fan 85 cool air is blown against metal pipe 84 for the purpose of cooling. Namely, pump 83 makes fluid 54 run out, after passage through transparent cell 91 in the casing 57 via tube 65. Further through cooler 80, then fluid 54 returns to pump 83 tube 65 and metal pipe 84. At transparent cell 91 and cooler 80, the fluid 54 which absorbs infrared light and heated thereby, in cooled down while passing metal pipe 84.

[0023] Fig. 6 and 7 illustrate embodiment of polymerization and curing of composit resin inlay, herein the tip of light guide 56 is provided with small light guide 86. The tip of small light guide 86 is formed into triangle shape. The passed light through inside of small light guide 86 is emitted to outside as it is (shown in Fig. central lower side). Additionally, the light emitted throughout light guide 56, out side of the small light guide 86, impinges to cavitas 87 further disperses to side direction by reflection at the triangle-shaped position. The triangle-shaped portion mentioned above can be of ball like-shaped. After photopolymerizable adhesive is applied to inner siuface of cavitas 87 of teeth 88, composit resin inlay field, and said small light guide 86 is inserted, accordingly light irradiated to composit resin inlay 89 for curing (Fig. 6). Further composit resin inlay 89 is filled into whole cavitas 87, light from light guide 56 is irradiated thereto without small light guide 86. Thus, composit resin inlay 89 can be polymerized and made curing even if it is carried out in a mouth for cavitas 87 with undercut.

[0024] In accordance with the present invention, lights emitted from the light source pass through the transparent cell charged with coolant so that the infrared lights are removed from the emitted lights, and the lights incident to the formed article. The about eighty percent of the infrared lights are cut off, for this reason temperature of the formed article hardly rises and photopolymerization resin used for the pattern is cured. The resin which

is polymerized and cured is taken out from the polymerization reactor so that the next step is readily performed. For this reason, the efficient work can be realized.

[0025] Further, in accordance with the present invention, temperature rise of the formed article is prohibited. For this reason, bad effect on the photopolymerization resin part of the formed article due to the temperature rise such as deformation, boiling of the liquid of monomer or the like is prohibited from generating so that the article having high precision and high strength with bubble free can be obtained.

[0026] Furthermore, in accordance with the present invention, the cooling efficiency is very high. Therefore, the lamp having power higher than that of the conventional one can be used. For this reason, time for polymerization and curing can be shorten so that efficiency of workability can be improved. With respect to the conventional photopolymerization reactor, it takes about three minutes to about four minutes to polymerize, while with respect to the apparatus of the present invention, it can be cured for about 30 to about 40 seconds to cure.

[0027] Further, in accordance with the present invention, the transparent cell is integrally formed of heat resistant glass. Therefore, even if heating and cooling are repeated for long interval in the state as to be equipped near the light source, the coolant is hardly leaked so that durability of the cell can be improved.

[0028] According to the present invention, there is provided a small-sized light irradiation for dental use, wherein the emission light from a light source transmit a cell for transmitting of visible light charged with fluid and because of elimination of infrared light therein and of emission of only visible light through light guide, the emission light can be heatless, accordingly irradiation against cavitas of teeth can be carried out without heating of the effected part. Therefore, the patient can be treated comfortably without pain resulted from heat. Further, according to the invention, there is provided a avoidance of harmful influence against human body by ultraviolet light irradiation, because elimination of ultraviolet light by a cell transmissive to visible light make it possible not to irradiate ultraviolet light against tissue in a mouth.

[0029] Further, according to the invention, there is provided a possibility to use emission lamp with higher power than prior because of extremely high efficiency of cooling of light source, therefore making it possible to carry out curing of inlay in a mouth while difficult because of insufficiency of the light dose in prior art, simultaneously to shorten time for polymerization of photopolymerizable resin. To improve working efficiency. Incidentally, photopolymerizing can be completed in about 30 to 40 sec. by the light irradiator of this invention.

Claims

1. Small-sized light irradiator for dental use, comprising:

(a) a light source (51) emitting visible, infrared and ultraviolet light and provided with a substantially half-ball shaped reflector (52) which converges at least visible light of said three kinds of light to a predetermined direction;

(b) a transparent cell (53, 91) transmissive to visible light, disposed on the emission side of said light source (51) to absorb infrared and ultraviolet

light; (c) a light guide (56) disposed such that light passing through said cell (53) impinges on its one side end and emits from its other side end which is directed to a predetermined direction; and

(d) a casing (57) with a handle (58) enclosing said light source (51) and transparent cell (53, 91) and provided with said light guide (56) to its one end,

characterized in that

(e) said transparent cell (53, 91) has a hollow space (69) therein charged with liquid coolant (54).

2. Small-sized light irradiator according to claim 1, **characterized** in that said transparent cell (53, 91) of visible light is connected to a pump (83) and a heat exchanger (84) via a tube (65) so as to circulate said liquid coolant.

3. Small-sized light irradiator according to claim 1 or 2, **characterized** in that said transparent cell (53) is composed of a disc-like shaped cell main body (67, 68) having a hollow space (69) therein, and two fine tubes (71) for fluid circulation fixed to said cell main body (67, 68) to communicate with said hollow space (69).

4. Small-sized light irradiator according to claim 1 or 2, **characterized** in that said transmission cell (91) of visible light is composed of a conical shaped cell main body (78) having a hollow space therein, and two fine tubes (79) for fluid circulation fixed to said cell main body (78) to communicate with said hollow space, wherein said conical shaped cell (91) is disposed such that a bottom portion of said conical shaped cell (91) is faced to the light source (51), a tip of said conical shaped cell (91) is faced to a side of one of said light guide (56).

5. Small-sized light irradiator according to one of the preceding claims, **characterized** in that said transparent cell (53, 91) is integrally formed so as to be combined with said reflector (52), and wherein said

reflector (52) has a duplex structure such that a space for communicating with the hollow space within said transparent cell (53, 91) is formed in the reflector (52).

6. Small-sized light irradiator according to claim 2, **characterized** in that a part (80) of said tubes (65) are wound so as to be in contact with an outside surface of said reflector (52), and wherein said tubes (65) are made of such a metal pipe as to have a good heat conductivity capable of absorbing heat of said reflector (52).

7. Small-sized light irradiator according to claim 2 or 6, **characterized** in that said pump (83) and said heat exchanger (84) are accommodated in said casing (57).

8. Small-sized light irradiator according to claim 2 or 6, **characterized** in that said pump (83) and said exchanger (84) are arranged in such a manner as to be separated from said casing (57).

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FIG. 1

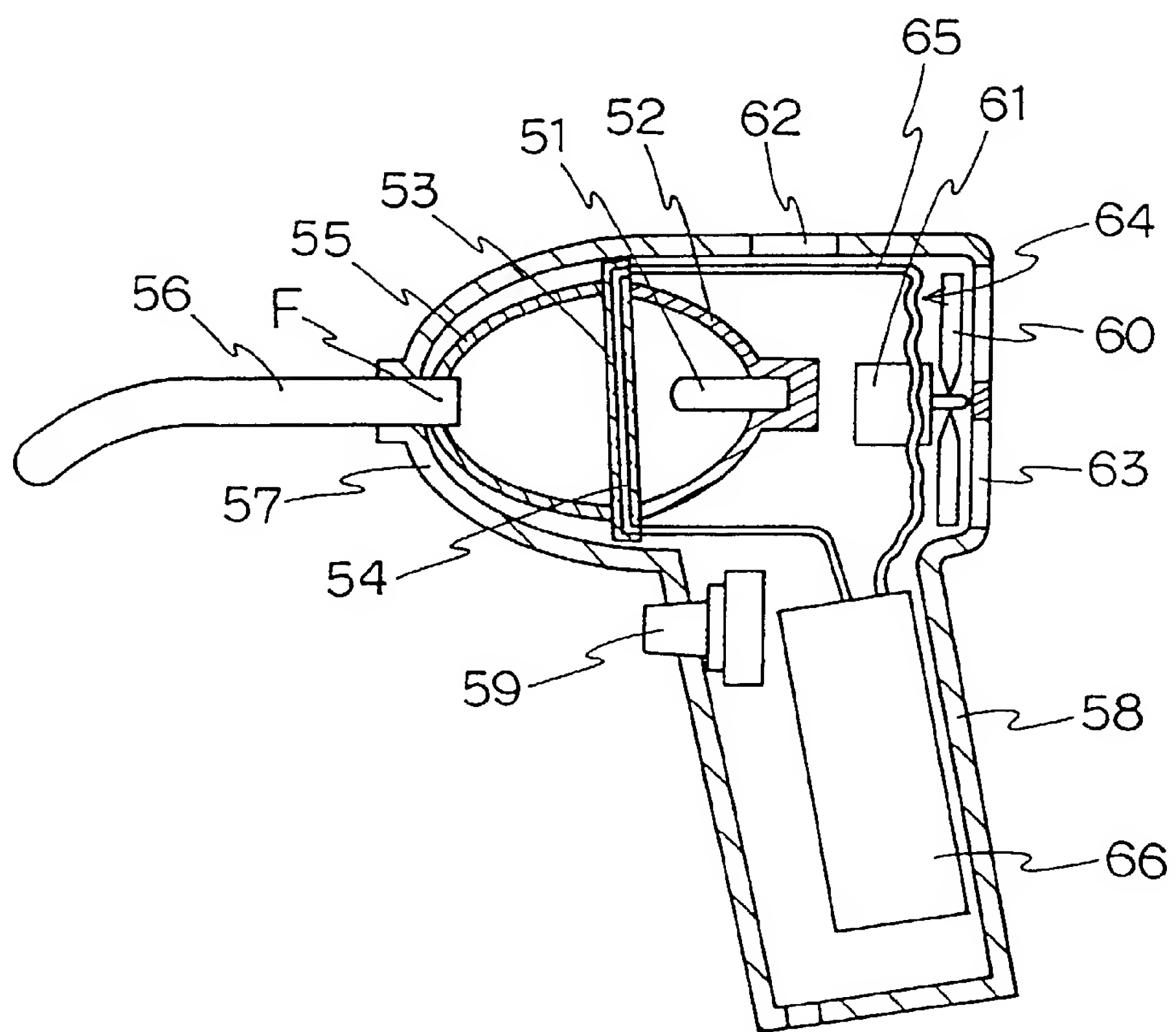


FIG. 2

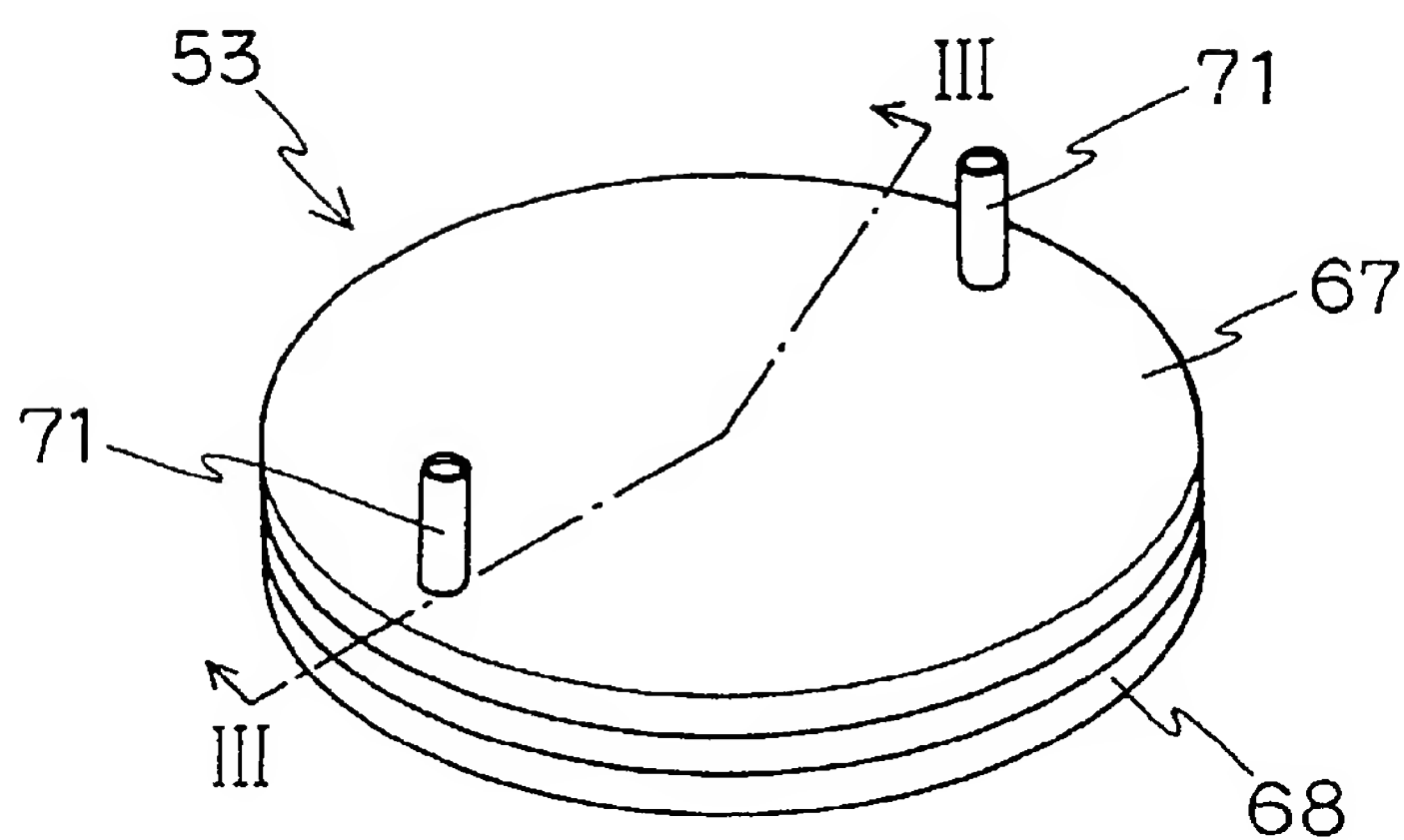


FIG. 3

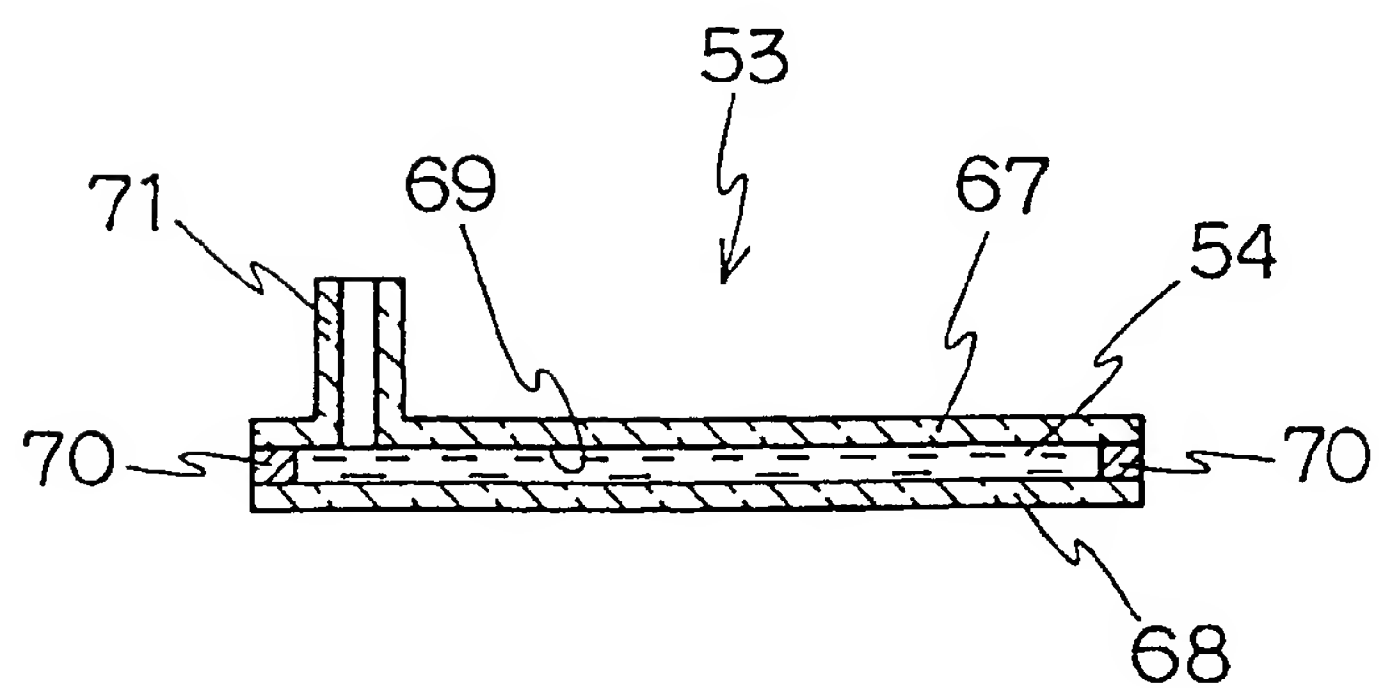


FIG. 4

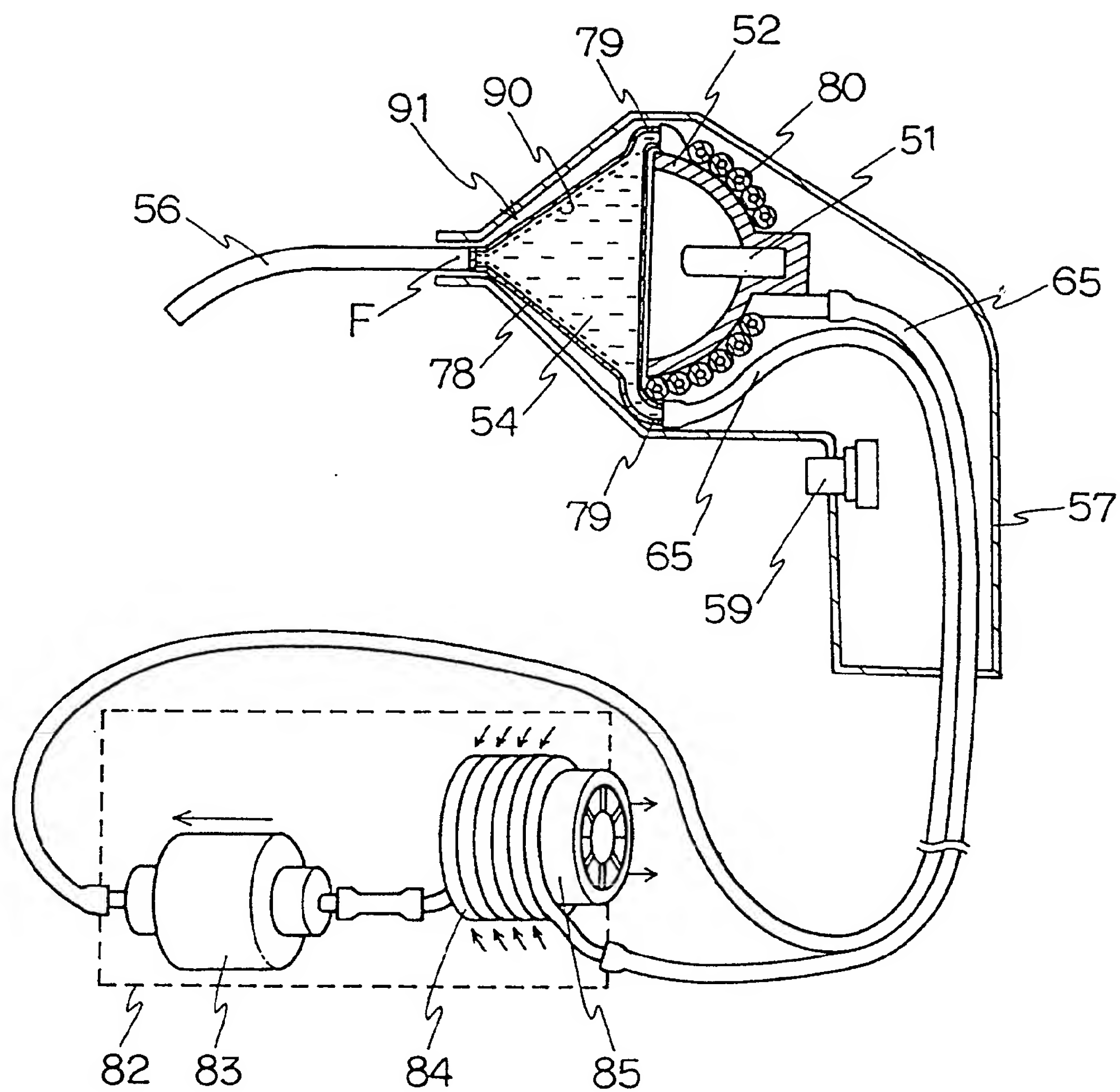


FIG. 5

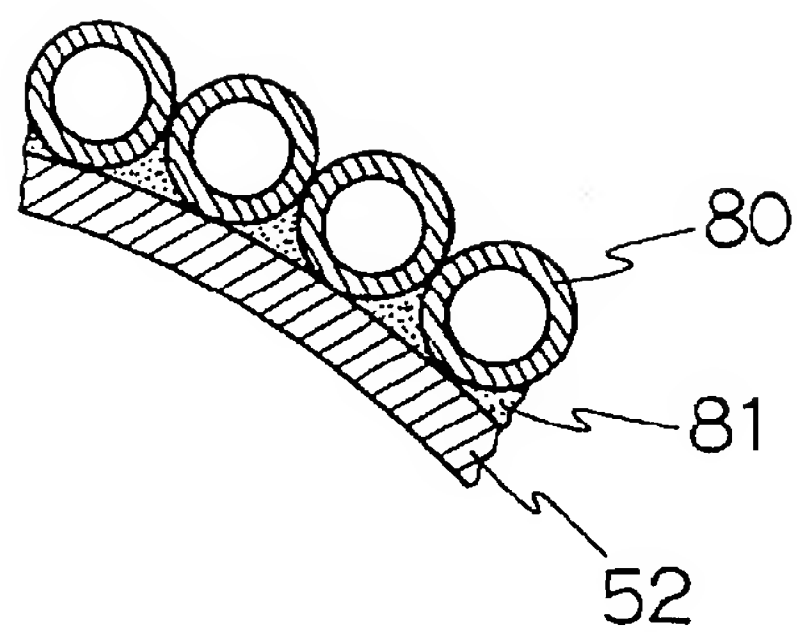


FIG. 6

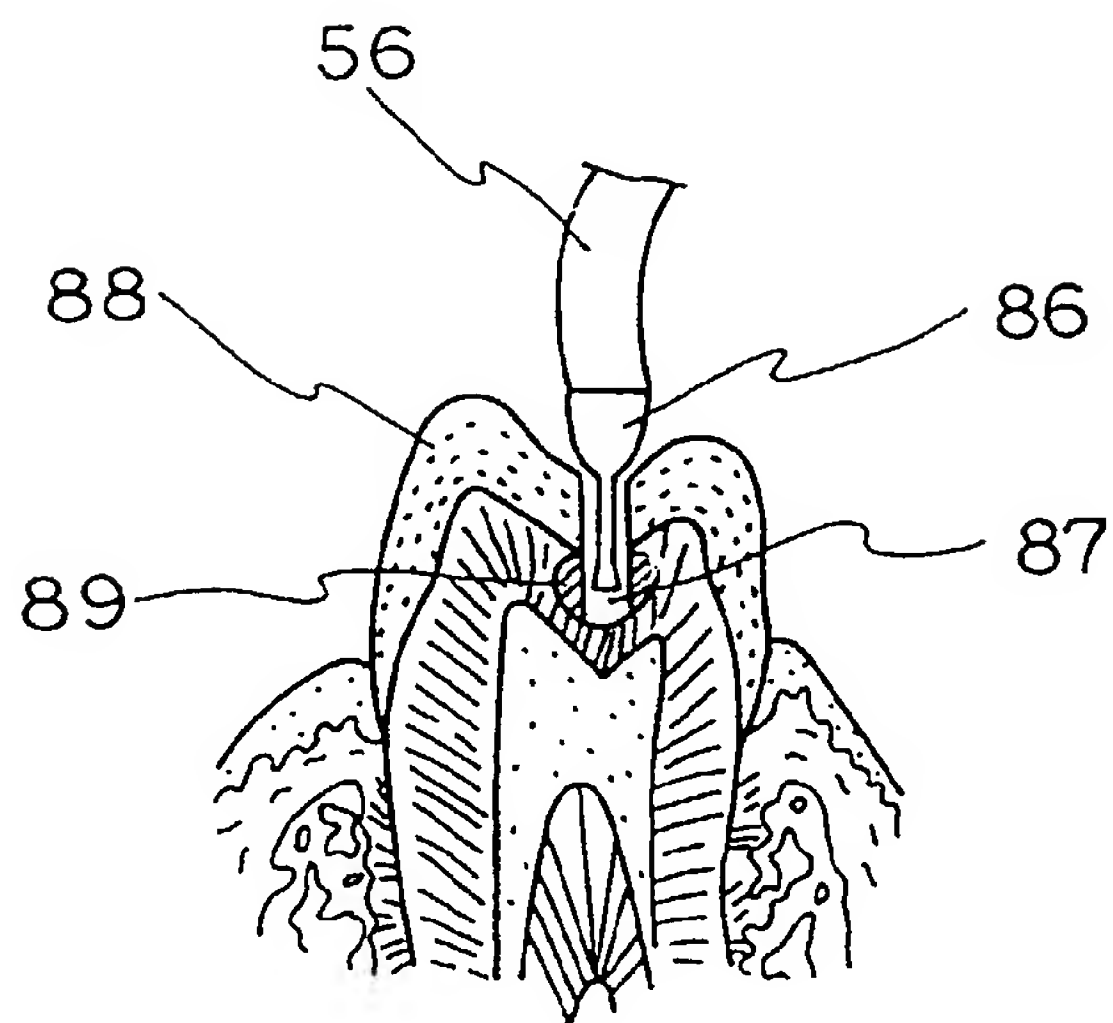
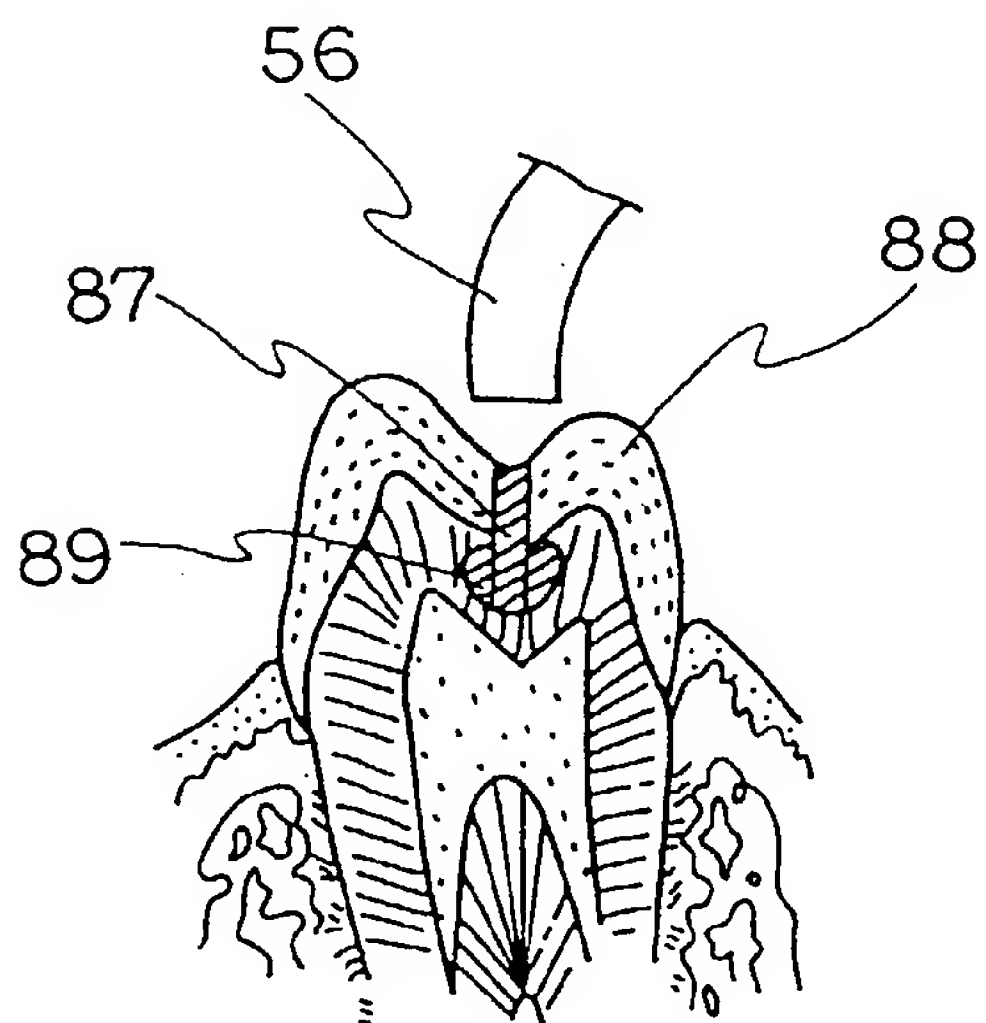


FIG. 7



(19)



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(54) **TOOTHBRUSH**

(57) The source of radiation of optical range (3) is built-in the cavity (2) of handpiece (1) of tooth brush comprising the transparent brush head (8). The combination of scattering properties of brush head (8), type of

radiation source (3) and brush transparency (7) allows to influence directly on different fields and tissues of oral cavity.

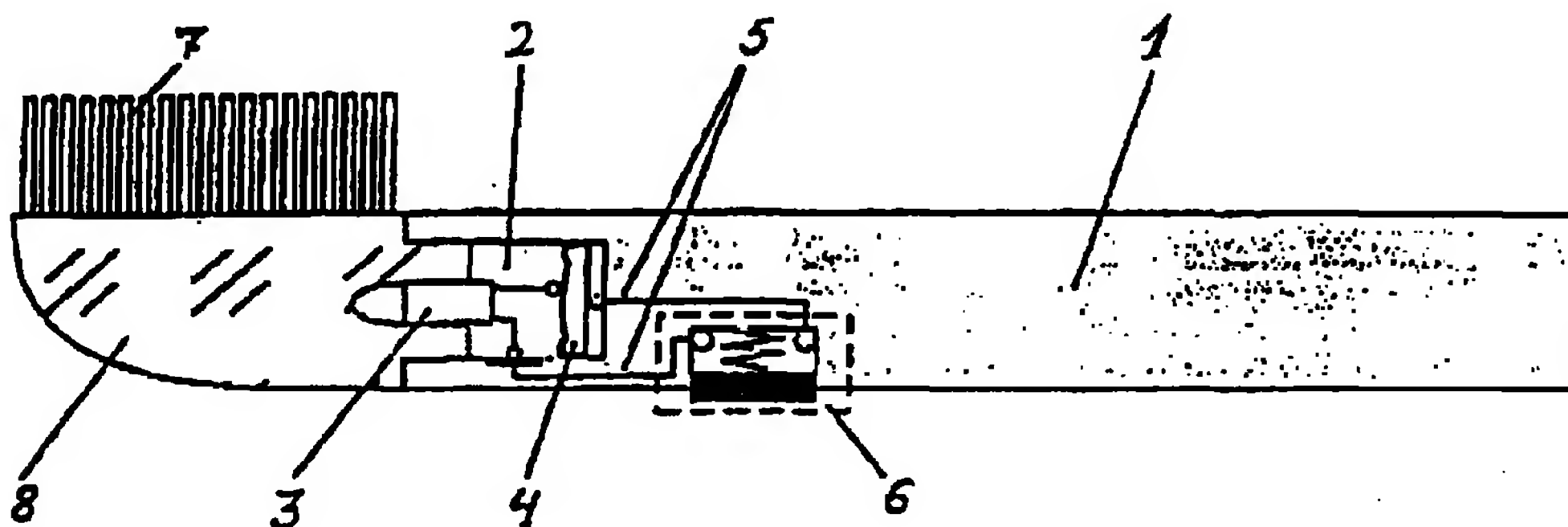


Fig. 1

EP 0 927 544 A2

Description

The field of engineering

[0001] The invention concerns to tooth brushes and can be used in dentistry for profilaxis and treatment of oral diseases.

The previous level of engineering

[0002] It is known the tooth brush (PCT N90/0906, A61 N1/32, A46 B15/00 date of the publication 23.08.90) comprising the electrode on the handle and the electrode with sharpened edges in the base of bristle. The electronic circuit providing the conditions of application of bipolar pulse train (especially with 50 Hz frequency) to oral tissues and LED indicating the operation of electronic circuit are mounted inside the brush handle.

[0003] The main disadvantage of above device is that it is impossible to make the influence on teeth except the gum tissue.

[0004] It is known also the tooth brush which is the closest one from the technical point of view and can be accepted as a prototype (Japan N3-15883, A46 B15/00, A61 N5/06, D01 F8/04 date of the publication 04.03.91) comprising the handle with built-in power supply, heater and head with bristle made of special thermoactive material radiating in far infrared range.

[0005] The main disadvantage of the prototype is the absence of radiation providing the profilaxis and treatment influence on teeth and gum.

The subject of the invention:

[0006] The problem solved by present invention consists of the creation of the tooth brush providing the profilaxis and treatment influence on tooth tissues and soft oral tissues.

[0007] The specified problem is solved under the realization of the invention due to achievement of technical result consisting of application of radiation of optical range that provides the antiinflammatory and caries protective influence on oral tissues as well stimulates their regeneration.

[0008] The specified technical result under realization of the invention is achieved due to the fact that in the tooth brush comprising the handpiece with cavity, brush head with bristle and built-in the handpiece cavity electrically connected through the switcher the radiation source and the power supply, the radiation source is represented by the source of radiation of optical range and brush head is made of transparent material and may be disconnected from the handpiece.

[0009] The said light source may be represented by laser diode or light emitting diode.

[0010] The said light source may be represented by a filament lamp and handpiece is made of color transpar-

ent material.

[0011] The said brush head may contain the light scattering materials.

[0012] The said brush head may have the reflecting or back scattering coating and bristle is made of transparent material.

[0013] The said brush head may contain the photoluminescent substances especially dyes.

[0014] It is well known the phisiotherapeutic influence of visible and near UV and IR radiations which at low doses make the biostimulating action on tissues. The most efficient is the laser radiation (AS.Kryuk., V.A.Mostovnikov, I.V.Khokhlov, N.S.Serdyuchenko. Therapeutic efficiency of low-intensity laser radiation. Minsk: Science & Engineering, 1986. V.E.Illarionov. The principles of laser therapy. M. Published by "RESPECT" of "INOTECH-Progress" Co.)

[0015] It is found out the antibacterial and antiinflammatory action of UV (330-380 nm), blue (440-450 nm) and green (514-590 nm) radiation. Besides that the red (630-640 nm) and near IR (830-1300 nm) radiation provides also the profilaxis and caries treating influence.

[0016] The profilaxis influence against caries is provided by irradiation of odontoblasts and tooth pulp due to waveguide effect of light propagation in the enamele prisms and dentinal tubules (see G.B.Altshuler, V.N.Grisimov. "The effect of waveguide light propagation in human tooth". Doklady AN USSR, v.310, N5, pp.1245-1248, 1990; G.B.Altshuler, V.N.Grisimov. "New optical effects in the human hard tooth tissues". Proc. SPIE. Lasers and Medicine, v.1353, pp97-102, 1991)

[0017] While the gums are irradiated both the antiparadontosis action and penetration of light inside teeth take place. The radiation is most efficient in the combination with massage of gums because the pressuring of alive soft tissue causes the increase of its transparency (see G.A.Askaryan "The increasing of transmission of laser and other radiation through the soft turbid physical and biological media". Kvantovaya Elektronika, v.9, N7, 1982, pp.1370-1383).

[0018] The useful irradiation of a whole oral cavity is provided in the claimed tooth brush due to the presence of light source connected to the electrical power supply and transparent brush head which can be made of light scattering material.

[0019] The types of light sources are determined by the necessity of application of light with specified spectral parameters and dose that are useful for specified type of hard and soft oral tissues.

[0020] More intensive irradiation of teeth and gums are provided with tooth brush that has the transparent bristle and reflecting or back scattering coating of a brush head.

[0021] The photoluminescent substances especially the dyes being introduced into the brush head provide practically all the useful spectral range of oral cavity radiation under the influence of a single shortwave, for example, UV or blue light source.

[0022] The author suppose that the set of claims is the new one as well the engineering satisfies the criterion of invention.

The brief description of figures:

[0023] The subject of the invention is specified by the figures, where

fig.1 represents the tooth brush which comprises the radiation source in the form of laser diode or light emitting diode connected to the power supply through the switcher and transparent brush head..

fig.2 represents the tooth brush which comprises the radiation source in the form of filament lamp and brush head made of color transparent material.

fig.3 shows the tooth brush which brush head has the reflecting coating and bristle is transparent.

The best version of the invention:

[0024] The tooth brush (fig.1) comprises the hand-piece 1 with cavity 2, the radiation source 3 built-in the handpiece cavity and electrically connected to the power supply 4 through the contacts 5 of switcher 6. The bristle 7 is fixed on the transparent brush head 8.

[0025] When the filament lamp is used as a radiation source 3 (fig.2) the brush head 8 is made of color transparent material.

[0026] The brush head 8 may be covered by reflecting coating 9 (fig.3) as well it may be made of light scattering material and covered by it. In this case the bristle 7 is transparent.

[0027] The device operates in a following way. After the power supply of radiation source 3 is switched on by pressing the button of switcher 6 the radiation from the source 3 reaches the body of brush head 8 and gets in the oral cavity.

[0028] If the filament lamp is used as a radiation source 3 the spectral filter cutting the desirable spectral range should be applied because of the wide spectral band of the source. The brush head made of the color (green, blue or red) transparent material may play the role of such filter.

[0029] If the bristle is made of the transparent material especially in that case when the brush head 8 is covered by reflecting coating 9 or when the radiation is scattered within the brush head the most part of radiation reaches the bristles, concentrates in them and then reaches the places of contact between bristle 7 and teeth or gum tissues.

[0030] Photoluminescent impurities, for example, dyes inside the brush head 8 provide the irradiation of oral cavity not only by radiation delivered from the radiation source 3 but also by radiations which spectral parameters are defined by Stokes law.

[0031] The wavelength of radiation emitted by the photoluminescent substances is always longer than the

wavelength of radiation source 3. If them is a single UV or blue radiation source it allows to deliver to the oral cavity the other desirable spectral components of visible and infrared light.

[0032] The example of claimed device is the following: laser diodes are SDL-2380-S with 810 nm radiation wavelength and SDL-7430 with 675 nm radiation wavelength (see Product Catalog SDL "Semiconductor Diode Lasers" 1995), light emitting diodes are LEDS-5 and LEDS-3 (blue, green, red) (see Catalog "RS components", Viena, 1995): the low-dimension power supply is VARTA chrom 547.

The industrial application:

[0033] Thus taking into account above the claimed device allows to solve the problem of profilaxis and treatment influence on oral tissues

Claims

1. A tooth brush comprising:

a handpiece with cavity;
a removable brush head with bristle;
a light source; and
a power supply,
wherein said light source and power supply are built-in handpiece and brush head is made of transparent material.

2. The invention as defined in claim 1 wherein said light source is a laser diode.

3. The invention as defined in claim 1 wherein said light source is a light emitting diode.

4. The invention as defined in claim 1 wherein said light source is a filament lamp and brush head is made of color transparent material.

5. The invention as defined in claim 1 wherein said brush head contains light scattering materials.

6. The invention a defined in claim 1 wherein said brush head has reflecting or back scattering coating and bristle is transparent.

7. The invention as defined in claim 1 wherein said brush head contains photoluminescent substances.

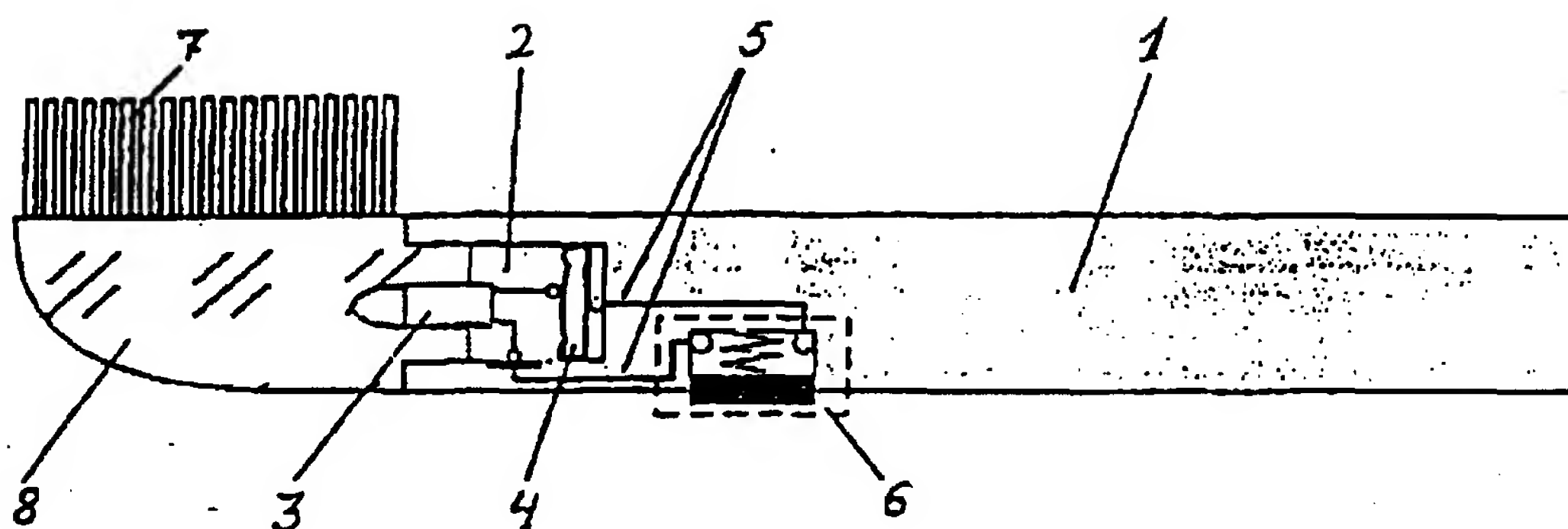


Fig .1

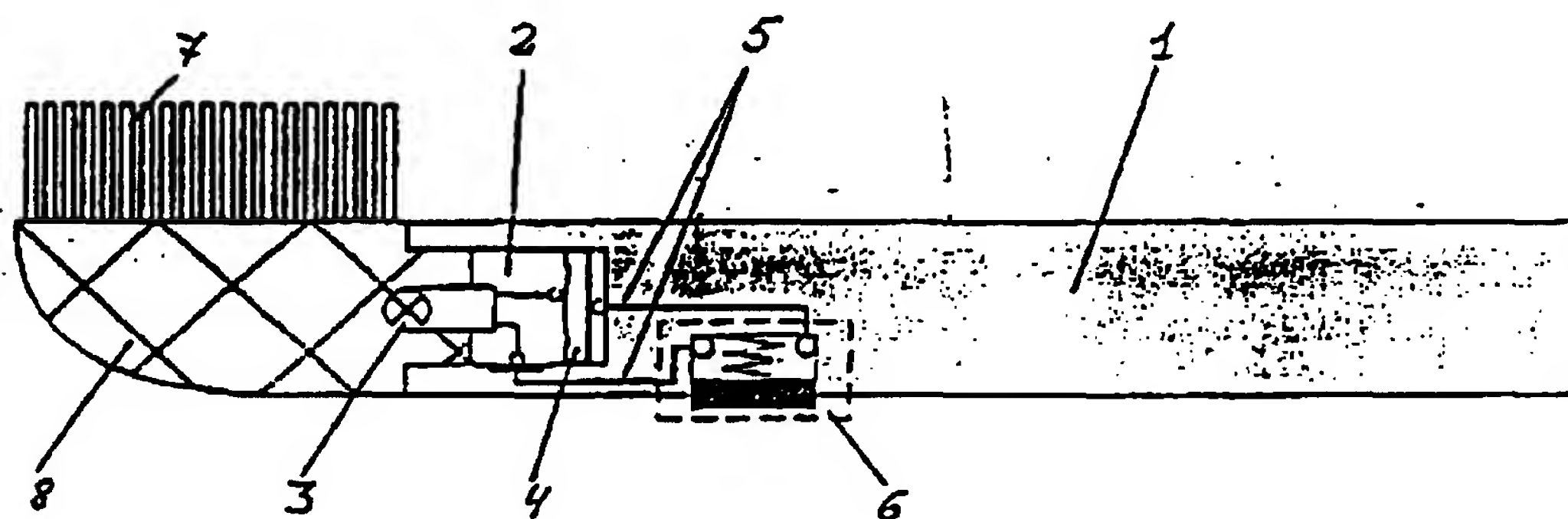


Fig .2

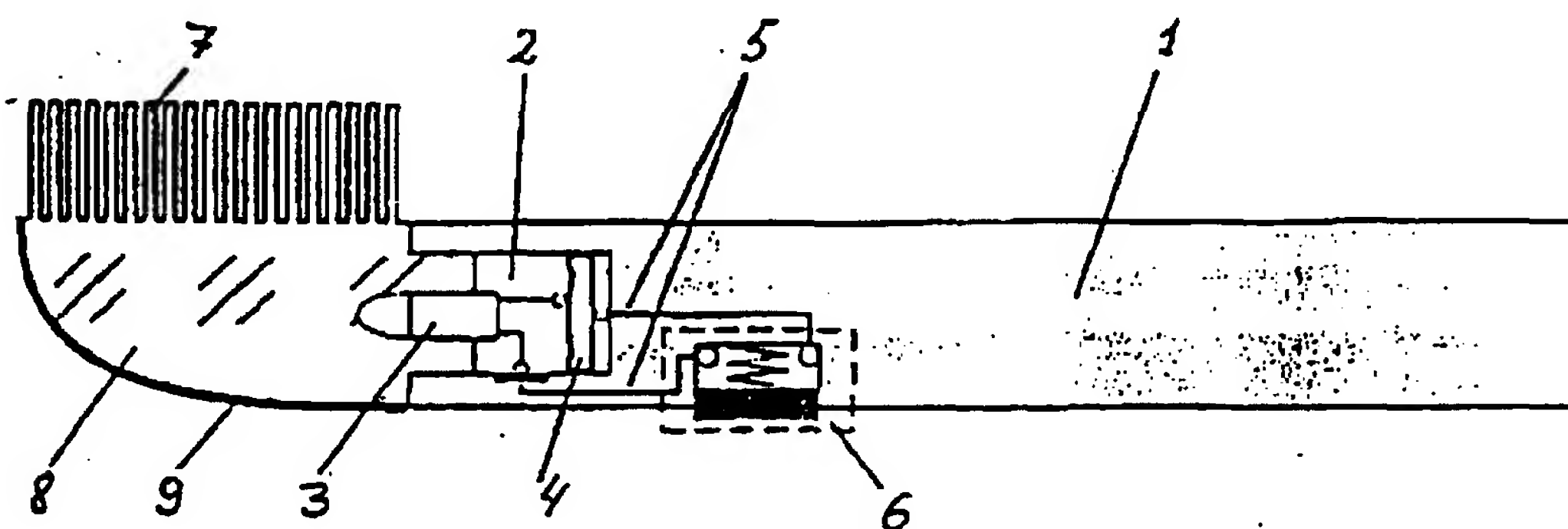


Fig .3

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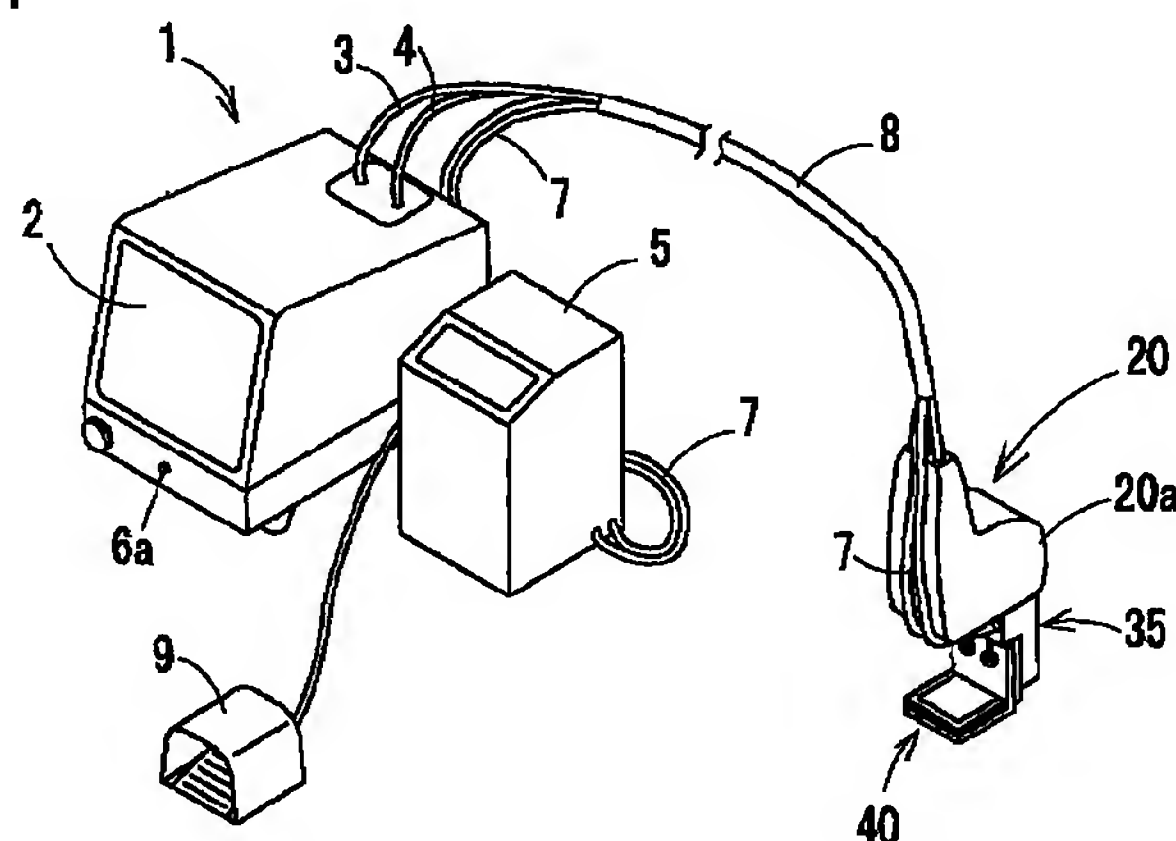
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(54) Laser skin treatment apparatus

(57) A laser treatment apparatus which is used to treat an affected part of a patient by irradiating a treatment laser beam to the affected part is disclosed. The apparatus includes a laser irradiation unit (1, 20) provided with a laser irradiation optical system (4, 10, 21, 22, 23, 24, 25) for delivering the laser beam to the affected part, a contact member (40) including a contact face (42) which is brought into contact with at least one of the affected part and a periphery of the affected part, a cooling unit (35) for cooling at least the contact face (42) of the contact member (40), a detector (15, 31, 51,

51', 60, 70, 80) for detecting at least one of a temperature of a periphery of contact face (42) made contact with the affected part, a temperature of the contact member (40) or the cooling means (35), a contact state of the contact face (42) with respect to the affected part, and a relative substantially horizontal movement of the contact member (40) with respect to the affected part, and an irradiation controller (15) for controlling laser irradiation based on a result of detection by the detector.

FIG.1



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Description

[0001] The present invention relates to a laser treatment apparatus which is used for treatment such as depilation, removal of wrinkles and birthmarks with a laser beam being irradiated to an affected part (a treatment part) of a patient.

[0002] When a laser treatment apparatus is used for performing treatment such as depilation to a patient by irradiating a laser beam to an affected part of the skin of the patient, the affected part is cooled before the laser irradiation in order to alleviate pain which would be caused by the laser irradiation. As such a method to cool the affected part, conventionally, there have been known a method of spraying nitrogen gas on the affected part and a method of decreasing the temperature of the affected part by making a cooling device contact with the affected part.

[0003] For execution of the laser irradiation, the positional relationship between the affected part and a laser irradiation unit such as a handpiece provided in the laser treatment apparatus must be stabilized. Therefore there has been known an apparatus arranged to have a support member (support base) which is brought into contact with the skin for stably supporting the irradiation unit. Furthermore, there is also an apparatus arranged to have a member serving both as the cooling device and the support member.

[0004] However, the above conventional apparatus may have possibilities that the laser irradiation is executed when an operator does not intend to do, for example, when the affected part is not sufficiently cooled or when the positional relationship between the affected part and the irradiation unit is not stabilized, etc. In such the cases, the unintentional laser irradiation may cause damage to the affected part and the parts outside thereof. The conventional apparatus is arranged to cool uniformly the affected part in spite of the condition thereof. Thus, the cooling could not be efficiently carried out.

[0005] The present invention has been made in view of the above circumstances and has an object to overcome the above problems and to provide a laser treatment apparatus capable of preventing laser irradiation under inappropriate conditions to an affected part of a patient, and capable of efficiently cooling the affected part.

[0006] Additional objects and advantages of the invention will be set forth in part in the description which follows and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention may be realized and attained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

[0007] To achieve the purpose of the invention, there is provided a laser treatment apparatus which is used to treat an affected part of a patient by irradiating

a treatment laser beam to the affected part, the apparatus including: a laser irradiation unit provided with a laser irradiation optical system for delivering the laser beam to the affected part; a contact member including a contact face which is brought into contact with at least one of the affected part and a periphery thereof; cooling means for cooling at least the contact face of the contact member; detection means for detecting at least one of a temperature of a periphery of the contact face made contact with the affected part, a temperature of the contact member, a temperature of the cooling means, a contact state of the contact face with respect to the affected part, and a relative substantially horizontal movement of the contact member with, respect to the affected part; and irradiation control means for controlling laser irradiation based on a result of detection by the detection means.

[0008] In the above apparatus according to the present invention, the irradiation control means controls the laser irradiation based on the detection results by the detection means in order to irradiate the laser beam to the affected part only if appropriate conditions for the laser irradiation are satisfied. Accordingly, the laser beam can be prevented from irradiating the affected part under inappropriate conditions for the laser irradiation, thus preventing damage by the laser beam to the affected part of the patient and the parts outside the affected part.

[0009] Preferably, in the above laser treatment apparatus, the detection means includes first temperature detection means for detecting the temperature of the periphery of the contact face made contact with the affected part, and the apparatus further includes temperature control means for controlling cooling operations of the cooling means based on a result of detection by the first temperature detection means.

[0010] It is preferable that the detection means further includes contact detection means for detecting the contact state of the contact face with respect to the affected part and second temperature detection means for detecting the temperature of the contact member or the cooling means; and the temperature control means controls cooling operations of the cooling means based on a result of detection by the second temperature detection means when the contact detection means detects that the contact face of the contact member is apart from both of the affected part and the periphery thereof.

[0011] Preferably, the contact detection means detects the contact state of the contact face with respect to the affected part based on the result of detection by the first temperature detection means.

[0012] Preferably, the detection means includes a contact detection means for detecting the contact state of the contact face with respect to the affected part, and when the contact detection means detects that the contact face is in contact with at least one of the affected part and the periphery thereof, the irradiation control

means enables laser irradiation after a lapse of a predetermined time.

[0013] It is preferable that the detection means further includes temperature detection means for detecting the temperature of the periphery of the contact face made contact with the affected part, and the contact detection means detects the contact state of the contact face with respect to the affected part based on a result of detection by the temperature detection means.

[0014] Preferably, the detection means includes movement detection means for detecting a relative moving amount of the contact member in a substantially horizontal direction with respect to the affected part, and the irradiation control means precludes laser irradiation when the movement detection means detects that the moving amount of the contact member exceeds a predetermined reference.

[0015] According to another aspect of the present invention, there is provided a laser treatment apparatus which is used to treat an affected part of a patient by irradiating a treatment laser beam to the affected part, the apparatus including; a laser irradiation unit provided with a laser irradiation optical system for delivering the laser beam to the affected part; a contact member including a contact face which is brought into contact with at least one of the affected part and a periphery thereof; cooling means for cooling at least the contact face of the contact member; first temperature detection means for detecting a temperature of a periphery of the contact face made contact with the affected part; and temperature control means for controlling cooling operations of the cooling means based on a result of detection by the first temperature detection means.

[0016] It is preferably that the above laser treatment apparatus further includes contact detection means for detecting the contact state of the contact face of the contact member with respect to the affected part, second temperature detection means for detecting a temperature of the contact member or the cooling means; and when the contact detection means detects that the contact face is apart from both of the affected part and the periphery thereof, the temperature control means controls cooling operations of the cooling means based on a result of detection by the second temperature detection means.

[0017] Preferably, the contact detection means detects the contact state of the contact face of the contact member based on the result of detection by the first temperature detection means.

[0018] Preferably, the laser treatment apparatus further includes a support member for supporting the laser irradiation unit on the affected part, the support member including the contact member.

[0019] Preferably, the laser treatment apparatus further includes a laser transmission member made of material that is good in thermal conductivity and transmittable to the laser beam, wherein the contact face includes at least a face of the laser transmission mem-

ber.

[0020] The accompanying drawings, which are incorporated in and constitute a part of this specification illustrate an embodiment of the invention and, together with the description, serve to explain the objects, advantages and principles of the invention.

[0021] In the drawings,

Fig. 1 is a perspective view of a laser treatment apparatus in a first embodiment according to the present invention;

Fig. 2 is a sectional view of a cooling unit and a part of a scanner head of the apparatus in the embodiment;

Fig. 3 is a block diagram of main elements of a control system of the apparatus in the embodiment;

Fig. 4A is a bottom view of a window unit of the apparatus;

Fig. 4B is a bottom view of a window unit in another example;

Fig. 5 is a sectional view of showing a structure of indirectly detecting temperatures of an affected part in a second embodiment of the apparatus;

Fig. 6 is sectional view of showing a structure of detecting relative movements of a handpiece to the an affected part in a sixth embodiment of the apparatus;

Fig. 7A is a schematic view of an internal structure of a contact section, seen from bottom, in the sixth embodiment;

Fig. 7B is a front view of a rotating plate of the contact section in the sixth embodiment;

Fig. 8 is a schematic view of a structure of detecting temperatures of an affected part by use of a temperature sensor of a non-contact type in a third embodiment of the apparatus; and

Fig. 9 is a flowchart of showing laser irradiation control in a fourth embodiment of the apparatus.

[0022] A detailed description of a preferred embodiment of a laser treatment apparatus embodying the present invention will now be given referring to the accompanying drawings.

[0023] Fig. 1 is a perspective view of a laser treatment apparatus in a first embodiment according to the present invention.

[0024] A main unit 1 of the laser treatment apparatus is provided with a large-size liquid crystal display (LCD) 2 at the front face. The LCD 2 is a touch panel whereby an operator can input various settings by depressing operation keys (items) displayed on a screen. A communication cable 3 and a fiber cable 4 are provided extending from the top of the main unit 1 to a handpiece 20 to connect therebetween.

[0025] Inside of the main unit 1, there are provided a laser source 10, a laser source 11, and others (see Fig. 3). The laser source 10 emits a near-infrared laser beam of a wavelength of 800-820nm. This laser beam is

used for depilation as a treatment laser beam. The laser source 11 emits a red visible laser beam of a wavelength of 620-650nm, which is used for aiming. The laser beams emitted from the laser sources 10 and 11 are delivered to the handpiece 20 through the fiber cable 4.

[0026] The handpiece 20 is constructed of a scanner head 20a containing an optical system and others for allowing the laser beam delivered thereto through the fiber cable 4 to scan, and a cooling unit 35 for cooling the skin of a patient by contacting with the skin.

[0027] Numeral 5 is a chiller for supplying coolant to the handpiece 20 (the cooling unit 35). Two tubes 7 connected with the chiller 5 are made into a bundle together with the communication cable 3 and the fiber cable 4, forming a single convergence cable 8 connected to the handpiece 20. Numeral 9 is a footswitch for generating a trigger signal to instruct start of laser irradiation. Numeral 6a is an indication lamp for informing the operator of that the laser beam is enabled to be irradiated. Numeral 6b is an indication buzzer for informing the operator of the same (see Fig. 3).

[0028] Fig. 2 is a sectional view of the cooling unit 35 and a part of the scanner head 20a of the handpiece 20. This scanner head 20a includes a first mirror 23 and a second mirror 24. Those first and second mirrors 23 and 24 are rotated (swung) by a first galvanometer 23a and a second galvanometer 24a respectively to deflect a laser beam to move an irradiating point in an X- and Y- directions. The laser beam is thus allowed to scan a wide area.

[0029] The laser beam delivered from the main unit 1 through the fiber cable 4 enters the scanner head 20a, wherein the beam is deflected by a mirror 21 and made into parallel luminous flux by a collimator lens 22. Then, the luminous flux is deflected by the first and second mirrors 23 and 24 to move the irradiating point in the X- and Y- directions, passing through a condenser lens 25, thereby forming a circular spot beam, which is of a diameter of about 5mm in the present embodiment. The laser beam is irradiated as the spot beam onto the affected part (treatment part).

[0030] It is to be noted that the position and the focal distance of the condenser lens 25 are determined such that the laser beam projected from the scanner head 20a is focused on or near an underside of a first window 42 (i.e., a contact side with the affected part). Therefore, when the cooling unit 35 (the first window 42) is made contact with the affected part, the scanner head 20a can stably be held at a substantially constant distance from the affected part. The cooling unit 35 also serves as a support member for supporting the scanner head 20a.

[0031] The cooling unit 35 is constructed of a scanner support base 26 and a window unit 40. The support base 26 is made of polyacetal resin which has an excellent heat-insulating property. This support base 26 is fixed under the scanner head 20a. A window fixing plate

27 made of aluminum which is good in thermal conductivity is disposed inside the base 26 and is fastened to the base 26 by screws tightened from the side of the base 26 (i.e., perpendicularly to the drawing paper of Fig. 2). Numeral 28 is a Peltier element which is an electronic heat exchanger. This Peltier element 28 is disposed between the fixing plate 27 and a cooling plate 29 made of aluminum and disposed in the base 26. A current is applied to the Peltier element 28 to pass there-through so that the side contacting with the fixing plate 27 functions as a heat-absorbing side (a cooling side), while the opposite side contacting with the cooling plate 29 functions as a heat-radiating side. The cooling plate 29 is provided therein with a flow passage through which the coolant circulates. The coolant cooled in the chiller 5 is delivered to the cooling unit 35 through the tubes 7 and fed to the cooling plate 29 through a water pipe 30 provided in the cooling unit 35, circulating through the inside of the cooling plate 29. The cooling plate 29 can thus absorb the heat radiated from the Peltier element 28.

[0032] Numeral 31 is a second temperature sensor attached to the lower end of the fixing plate 27. This second temp. sensor 31 detects the temperature of the fixing plate 27. The controller 15 controls the temperature of the Peltier element 28 based on the result of detection by the second temp. sensor 31. The detail thereof will be described later.

[0033] The window unit 40 is constructed of a window frame 41, the first window 42, a heat-insulating board 43, a second window 44, a cover 45. The details of those members are as follows.

[0034] The first window 42 is made of transparent sapphire glass which is good in thermal conductivity. This first window 42 is brought into contact with the skin of the patient for the laser treatment. The window frame 41 has a substantially L-shaped section as shown in Fig. 2, including a vertical part 41a and a horizontal part 41b, and holds the first window 42 in the horizontal part 41b. The heat-insulating board 43 is made of polyacetal resin which has a good heat-insulating property. This board 43 is given the shape of a rectangular frame. The second window 44 is made of transparent glass which is inferior to the first window 42 in thermal conductivity, for example, BK7 (the classification symbol of SHOT Co.) generally used as optical glass. The cover 45 is made of aluminum and has an opening. The window unit 40 having the above arrangement can transmits the laser beam discharged from the scanner head 20a toward the affected part.

[0035] The window frame 41 is made of aluminum which is good in thermal conductivity. The vertical part 41a of the frame 41 is formed with two U-shaped slots (not shown) in the upper portion. Thus, the frame 41 is detachably secured to the fixing plate 27 by two screws 32 passing through the two slots and are threaded into the fixing plate 27. Such the arrangement enables attachment of a suitable window unit according to pur-

poses. Detaching the window frame 41 can be easily done by only loosening the screws 32 a little, without fully removing the screws 32, thereby allowing the frame 41 to move downward. On the other hand, attaching the window frame 41 is made by sliding the vertical part 41a of the frame 41 along the fixing plate 27 until the two U-shaped slots of the vertical part 41a are engaged with the two screws 32, and then tightening the screws 32. As cooled by the Peltier element 28, the fixing plate 27 cools the window frame 41 contacting therewith, thus cooling the first window 42.

[0036] The window frame 41 is formed with an opening in the horizontal part 41b formed horizontally extending and shaped as a rectangular frame. In the underside of the horizontal part 41b, the first window 42 is fitted with adhesive of good thermal conductivity. This first window 42 in the present embodiment is a square of about 40mm per side. On the upside of the horizontal part 41b, the heat-insulating board 43 is disposed and, furthermore, the second window 44 is fixed on the board 43 with adhesive of a good heat-insulating property to be shielded from the cooling. The cover 45 is adhered to the second window 44 to cover all the above members. With such the arrangement, there is provided a sealed space 48 (indicated by a dotted line in Fig. 2) which serves as a heat-insulating layer between the first and second windows 42 and 44 to enhance the heat-insulation effect between the windows configured as a double-window construction. Accordingly, even if the first window 42 is allowed to cool, the second window 44 will not easily cool. This can prevent the generation of condensation on the upper surface of the second window 44.

[0037] Numeral 50 is a heat-insulating board 50 made of polyacetal resin which has a good heat-insulating property. This board 50 is disposed, as shown in Fig. 2, between the window frame 41 and a first temperature sensor 51 and between the first window 42 and the first temp. sensor 51 to prevent the first temp. sensor 51 from making contact with both of the window frame 41 and the first window 42.

[0038] The first temp. sensor 51 is constructed of a sheet-type thermistor. This sensor 51 is attached to the window frame 41 along the frame shape of the bottom surface of the horizontal frame part 41b (see Fig. 4A) so that the surface of the first temp. sensor 51, opposite to the surface contacting with the heat insulating plate 50, becomes substantially flush with the bottom surface of the first window 42. Thus, when the bottom surface of the first window 42 is brought into contact with the skin of the patient, the surface of the first temp. sensor 51 makes contact with the skin at the same time, enabling detection of the temperature of the skin (the periphery of the affected part).

[0039] It is to be noted that although the first temp. sensor 51 is a sheet-type thermistor in the present embodiment, it is not limited thereto and may be modified to different arrangements if only the surface thereof can make contact with the skin to detect the tempera-

ture thereof at the same time when the bottom surface of the first window 42 is brought into contact with the skin. One example of such the arrangements is shown in Fig. 4B. In Fig. 4B, a first temp. sensor 51' is constructed to detect the temperature of a point on the skin.

[0040] The first temp. sensor 51 is connected to the communication cable 3 through a connection cable not shown and a connector. At the time of detaching the window unit 40, the connection cable is disconnected from the connector. This also enables an exchange of window units without any trouble.

[0041] Similarly to the case of the second temp. sensor 31 mentioned above, the controller 15 controls the temperature of the Peltier element 28 based on the detection result by the first temp. sensor 51. The detail thereof will be described later.

[0042] Numeral 46 is a heat-insulating board made of polyacetal resin and is fixedly attached to the vertical part 41a of the window frame 41 for preventing the window frame 41 from absorbing extraneous heat and also for heat-insulating the second window 44.

[0043] Next, operation of the laser treatment apparatus constructed as above will be described with reference to Fig. 3 which is a block diagram of main elements of a control system of the apparatus in the present embodiment.

[0044] The first galvanometer 23a, the second galvanometer 24a, the second temp. sensor 31, the first temp. sensor 51, the Peltier element 28, and others are connected to the controller 15 through the communication cable 3.

[0045] An operator operates setting keys displayed on the LCD panel 2 to set irradiation conditions for preparation for laser irradiation. While the first window 42 is not in contact with, or is apart from the affected part of the patient, the controller 15 controls the temperature of the Peltier element 28 so that a predetermined value is constantly detected by the second temp. sensor 31.

[0046] The contact/noncontact of the first window 42 with the affected part can be judged based on the result of temperature detection by the first temp. sensor 51. For instance, the threshold value for detection of the contact of the first window 42 with the affected part is set at 30°C. When the first temp. sensor 51 detects the temperature more than 30°C, the controller 15 judges that the first window 42 is in contact with the affected part. Alternatively, a contact sensor (a touch sensor) may be provided in the part or surface of the window unit 40 which is made contact with the skin.

[0047] While the controller 15 controls the temperature of the Peltier element 28 based on the result of temperature detection by the second temp. sensor 31, the controller 15 controls (interlocks) the laser source 10 to prevent the laser irradiation even if a trigger signal of instructing the laser irradiation is input from the footswitch 9. Alternatively, instead of direct driving of the laser source 10, a safety shutter may be controlled to be inserted into or removed from an optical path of the

laser beam.

[0048] The operator, after preparation of the main unit 1 for laser irradiation, holds the handpiece 20 by hand to bring the first window 42 into contact with the affected part (skin). Then, the controller 15 receives the result of detection by the first temp. sensor 51 and determines whether the detected temperature is equal to or more than the threshold value to detect the contact of the first window 42 with the affected part. When the detected temperature is the threshold value or more, the controller 15 recognizes that the first window 42 is in contact with the affected part. Upon recognition of the contact of the first window 42 with the affected part, the controller 15 stops control of the temperature of the Peltier element 28 based on the detection result by the second temp. sensor 31 and, alternatively, starts the control of the temperature of the Peltier element 28 based on the detection result by the first temp. sensor 51.

[0049] Contacting with the first window 42, the affected part is gradually cooled due to heat-absorption by the first window 42. The temperature variation occurring in the affected part also causes the temperature of the periphery of the affected part to decrease. The first temp. sensor 51 detects the temperature variation in the affected part and the periphery thereof.

[0050] When the temperature of the affected part detected by the first temp. sensor 51 does not reach an appropriate value (for example, 5°C in the present embodiment, which is referred to as a predetermined temperature) for laser irradiation, the controller 15 controls the temperature of the Peltier element 28 (the heat-absorbing side, or the cooling side) to further decrease regardless of the temperature detected by the second temp. sensor 31.

[0051] Decreasing the temperature of the heat-absorbing side of the Peltier element 28 enhances the heat-absorbing effect of the first window 42. This makes it possible to shorten the time needed until the temperature of the affected part reaches (decreases to) the predetermined temperature. When the detected temperature by the first temp. sensor 51 reaches the predetermined temperature, the controller 15 stops cooling the Peltier element 28. Simultaneously, the controller 15 releases the interlock of the laser source 10 to enable the laser beam to be irradiated to the affected part. Alternatively, the safety shutter may be removed from the optical path for enabling laser irradiation. The controller 15 causes the indication lamp 6a to light up and the indication buzzer 6b to sound in order to inform the operator of that the temperature of the affected part has reached the predetermined temperature and the laser irradiation is enabled.

[0052] After the indication by the lamp 6a and the buzzer 6b, the operator may instruct the laser irradiation by depressing the footswitch 9. Upon receipt of the trigger signal from the footswitch 9, the controller 15 controls the first and second galvanometers 23a and 24a respectively to allow the laser beam emitted from the

laser source 10 to scan a selected scanning area in the treatment part while irradiating. Alternatively, the controller 15 may be arranged to automatically start the laser irradiation upon release of the interlock of the laser source 10.

[0053] Upon completion of the laser irradiation, the first window 42 (the handpiece 20) is moved away from the affected part. This causes sudden variation in temperature detected by the first temp. sensor 51 because the sensor 51 detects the room temperature. When the controller 15 obtains a predetermined or more temperature variation (for example, a 5°C or more variation) in the detection result by the sensor 51 after completion of the laser irradiation, the controller 15 recognizes that the first window 42 has been moved away from the affected part, and controls the temperature of the Peltier element 28 based on the detected temperature by the second temp. sensor 31.

[0054] In the above first embodiment, the temp. sensor (the first temp. sensor 51) is provided near the first window 42 to directly detect a variation in temperature of the affected part. With this detection manner, the laser irradiation is controlled so that it is precluded until the detected temperature reaches the predetermined value. However the laser irradiation may also be controlled by the arrangements other than that described above. Some examples thereof will be described below.

[0055] In a second embodiment, the laser irradiation is controlled by indirect detection of the temperature of the affected part, instead of the direct detection of the same in the first embodiment. This indirect detection is executed by detecting a variation in temperature of the first window 42.

[0056] In the present embodiment, a temperature sensor 60 for detecting the internal temperature of the first window 42 is provided in the first window 42 at a position where the sensor 60 does not prevent the scanning of the laser beam (see Fig. 5). When the first window 42 held at a predetermined temperature is made contact with the skin, the temperature of the window 42 rises once. The window 42 is then cooled by the Peltier element 28 into the predetermined temperature again. The controller 15 enables the laser irradiation when the temperature of the window 42 returns to the predetermined value (or reaches a permissible range of the predetermined temperature). In this case, the temp. sensor 60 is preferably disposed inside the first window 42 closer to the bottom surface (as closer as possible to the affected part), thus enabling speedup in detection of temperature variation.

[0057] In a third embodiment, a noncontact type temperature sensor is used to detect the temperature of the affected part through the first window 42 and others. This arrangement is shown in Fig. 8, where like elements corresponding to those in Fig. 2 are indicated by like numerals. Numeral 80 is a temperature sensor disposed in the scanner head 20a. The sensor 80 detects infrared energy radiated from the affected part to detect

the temperature of the affected part. Numeral 81 is a half mirror which reflects the major part of the laser beam, while transmitting an infrared light from the affected part.

[0058] In the above embodiments, the laser irradiation is controlled based on the temperature of the affected part, but it is not limited thereto. It may be arranged, for example, such that the laser irradiation is enabled when a predetermined time elapses after detection that the first window 42 is in contact with the affected part. The control in this case is explained below as a fourth embodiment referring to Fig. 9 showing a flowchart of the laser irradiation control.

[0059] After preparation of the main unit 1 (S1), the operator holds the handpiece 20 to bring the first window 42 into contact with the affected part. The controller 15 then determines whether the detected temperature by the first temp. sensor 51 (or the temp. sensor 60 or 80) is the threshold value or more (S2). When the detected temperature is the threshold value or more, the controller 15 recognizes that the first window 42 is in contact with the affected part (S2: YES). The controller 15 enables the laser irradiation after a lapse of a predetermined time (for example, 2 seconds in the present embodiment).

[0060] This predetermined time can be determined in the following manner. The first window 42 is in advance made contact with some different positions in the affected part to obtain a time needed until the temperature at each position reaches a proper value. Thus the controller 15 quantitatively determines the predetermined time. It may be arranged such that the controller 15 simultaneously detects a temperature variation occurring in the affected part through the first temp. sensor 51 (or the temp. sensor 60 or 80) and, when the temperature reaches the predetermined value before a lapse of the predetermined time, the laser irradiation is enabled even if the predetermined time does not lapse yet.

[0061] Furthermore, in a fifth embodiment, the laser irradiation may be controlled by only detection of contact/noncontact of the first window 42 with the affected part. In this case, the controller 15 detects the contact state of the window 42 based on a temperature variation detected by the first temp. sensor 51 (or the temp. sensor 60 or 80). The laser irradiation can thus be controlled based on the detection result by the sensor 51. Alternatively, two electrodes may be provided in a face of the window unit 40 which makes contact with the affected part, allowing the controller 15 to detect variation in current or resistance which occurs when the electrodes come into contact with the affected part. Instead thereof, a pressure detecting element may be used to allow the controller 15 to determine the contact/noncontact state of the first window 42, for example, by detecting a pressure exerted on the first window 42 when made contact with the affected part.

[0062] In a sixth embodiment, on the other hand,

the laser irradiation control can be executed if the handpiece 20 and the patient unintentionally move even during the laser irradiation. This arrangement is explained below with reference to Fig. 6. Fig. 6 shows the structure of the handpiece 20 shown in Fig. 2 with a contact section 70 added. Like elements corresponding to those in Fig. 2 are indicated by like numerals. The contact section 70 is provided with detecting members for detecting the contact state of the first window 42 with the affected part and the movement thereof in a substantially horizontal direction.

[0063] To be more specific, at the underside of the contact section 70 are provided a ball 71 and a microswitch 72. The ball 71 is rotatably held in the contact section 70 so as to partially protrude out of a housing of the contact section 70. The microswitch 72 is turned on when the underside of the contact section 70 comes into contact with the affected part.

[0064] Fig. 7A is a schematic view of the internal structure of the contact section 70, seen from bottom. Rollers 73a and 73b are rotatably provided in contact with the ball 71, both rollers being disposed in directions intersecting at right angles. Rolling of the ball 71 causes the rollers 73a and 73b to rotate respectively. Numerals 74a and 74b are rotating discs which are attached to shafts 75a and 75b of the rollers 73a and 73b, respectively. By rotation of the rollers 73a and 73b, the rotating discs 74a and 74b are rotated in the same directions as those of the rollers 73a and 73b.

[0065] Each of the rotating discs 74a and 74b is provided with a plurality of slits 77 circumferentially spaced as shown in Fig. 7B. Numerals 76a and 76b are photosensors, each of which is constructed of a light projecting element and a light receiving element. The photosensor 76a (76b) is disposed so that the rotating disc 74a (74b) is partially inserted between the light projecting element and the light receiving element. This mechanism is substantially similar to a movement detecting mechanism of a mouse generally used in personal computers.

[0066] The microswitch 72 and the photosensors 76a and 76b are connected to the controller 15 through the communication cable 3.

[0067] After preparation of the main unit 1 for the laser irradiation in a similar manner to the above embodiments, the operator moves the handpiece 20 by hand to bring the first window 42 into contact with the affected part. When the first window 42 is made contact with the affected part, pressing the microswitch 72, thereby transmitting a relevant signal to the controller 15 through the communication cable 3.

[0068] If the controller 15 has not received the signal from the microswitch 72, alternatively, if the temperature of the affected part has not reached the predetermined value, the controller 15 controls (interlocks) the laser source 10 to preclude the irradiation of the laser beam even if the trigger signal of instructing the laser irradiation is input.

[0069] Even though the laser irradiation is enabled and executed, the handpiece 20 or the patient unintentionally moves or shifts in some cases, thereby causing the contact section 70 to separate from the affected part. The microswitch 72 is thus turned off. Receiving no signal from the microswitch 72, the controller 15 stops the laser irradiation.

[0070] If the contact section 70 is moved in a substantially horizontal direction though it is maintained contact with the affected part, the interlock is also established due to the rolling of the ball 71 of the contact section 70 in correspondence to the moving amount of the contact section 70.

[0071] The rolling of the ball 71 causes the rollers 73a and 73b to rotate. The rotation of the roller 73a (73b) is transmitted to the rotating disc 74a (74b). The rotation of the disc 74a (74b) is detected by the photosensor 76a (76b), which transmits a detection signal to the controller 15. The controller 15 detects that the contact section 70 (namely, the handpiece 20) is relative moved with respect to the affected part based on the input detection signal in comparison with the signal from the photosensors 76a and 76b at the time of input of the trigger signal from the footswitch 9. The controller 15 stops the laser irradiation when the moving amount of the contact section 70 exceeds a predetermined amount. This moving amount can be obtained in the following manner. By the rotation of the rotating disc 74a (74b), the luminous flux projected by the light projecting element of the photosensor 76a (76b) is pulsed and received by the receiving element. The moving amount is thus calculated based on the number of pulses detected by the photosensor 76a (76b).

[0072] The above control can establish the interlock to stop the laser irradiation if the patient or the handpiece 20 unintentionally moves even during the laser irradiation, enabling the prevention of the laser irradiation to any parts other than the intended part.

[0073] As described above, in the above embodiments according to the present invention, the temperatures of the affected part and others are detected by the temp. sensors to prevent the laser irradiation to the affected part if it is not cooled enough for the laser irradiation, thereby reducing damage to the skin of the patient.

[0074] Detecting the contact/noncontact of the first window 42 with the affected part and the relative horizontal movement of the handpiece with respect to the affected part, the controller 15 operates to stop the laser irradiation when the affected part moves even during the laser irradiation. This makes it possible to prevent damage by the laser beam to unintended parts outside the affected part to be irradiated.

[0075] The present invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof.

[0076] The foregoing description of the preferred embodiment of the invention has been presented for

purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed, and modifications and variations are possible in light of the above teachings or may be acquired from practice of the invention. The embodiment chosen and described in order to explain the principles of the invention and its practical application to enable one skilled in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the claims appended hereto, and their equivalents.

Claims

1. A laser treatment apparatus which is used to treat an affected part of a patient by irradiating a treatment laser beam to the affected part, the apparatus including:

a laser irradiation unit (1, 20) provided with a laser irradiation optical system (4, 10, 21, 22, 23, 24, 25) for delivering the laser beam to the affected part;

a contact member (40; 41, 42, 43, 44, 45, 46, 48, 50) including a contact face (42) which is brought into contact with at least one of the affected part and a periphery thereof;

cooling means (35; 5, 7, 27, 28, 29, 30) for cooling at least the contact face (42) of the contact member (40);

detection means (15, 31, 51, 51', 60, 70, 80) for detecting at least one of a temperature of a periphery of the contact face (42) made contact with the affected part, a temperature of the contact member (40), a temperature of the cooling means (35), a contact state of the contact face (42) with respect to the affected part, and a relative substantially horizontal movement of the contact member (40) with respect to the affected part; and

irradiation control means (15) for controlling laser irradiation based on a result of detection by the detection means.

2. The laser treatment apparatus according to claim 1, wherein the detection means includes first temperature detection means (51, 51', 60, 80) for detecting the temperature of the periphery of the contact face (42) made contact with the affected part, and the apparatus further includes temperature control means (15) for controlling cooling operations of the cooling means (35) based on a result of detection by the first temperature detection means (51, 51', 60, 80).

3. The laser treatment apparatus according to claim 2, wherein the detection means further includes:

- contact detection means (15) for detecting the contact state of the contact face (42) with respect to the affected part; and
- second temperature detection means (31) for detecting the temperature of the contact member (40) or the cooling means (35); and
- the temperature control means (15) controls cooling operations of the cooling means (35) based on a result of detection by the second temperature detection means (31) when the contact detection means (15) detects that the contact face (42) of the contact member (40) is apart from both of the affected part and the periphery thereof.
4. The laser treatment apparatus according to claim 3, wherein the contact detection means (15) detects the contact state of the contact face (42) with respect to the affected part based on the result of detection by the first temperature detection means (51, 51', 60, 80).
5. The laser treatment apparatus according to claim 1, wherein the detection means includes contact detection means (15) for detecting the contact state of the contact face (42) with respect to the affected part, and when the contact detection means (15) detects that the contact face (42) is in contact with at least one of the affected part and the periphery thereof, the irradiation control means (15) enables laser irradiation after a lapse of a predetermined time.
6. The laser treatment apparatus according to claim 5, wherein the detection means further includes temperature detection means (51, 51', 60, 80) for detecting the temperature of the periphery of the contact face (42) made contact with the affected part, and the contact detection means (15) detects the contact state of the contact face (42) with respect to the affected part based on a result of detection by the temperature detection means (51, 51', 60, 80).
7. The laser treatment apparatus according to claim 1, wherein the detection means includes movement detection means (70; 71, 73, 74, 75, 76) for detecting a relative moving amount of the contact member (40) in a substantially horizontal direction with respect to the affected part, and the irradiation control means (15) precludes laser irradiation when the movement detection means (70) detects that the moving amount of the contact member (40) exceeds a predetermined reference.
8. A laser treatment apparatus which is used to treat an affected part of a patient by irradiating a treatment laser beam to the affected part, the apparatus including:
- a laser irradiation unit (1, 20) provided with a laser irradiation optical system (4, 10, 21, 22, 23, 24, 25) for delivering the laser beam to the affected part;
- a contact member (40) including a contact face (42) which is brought into contact with at least one of the affected part and a periphery thereof;
- cooling means (35) for cooling at least the contact face (42) of the contact member (40);
- first temperature detection means (51, 51', 60, 80) for detecting a temperature of a periphery of the contact face (42) made contact with the affected part; and
- temperature control means (15) for controlling cooling operations of the cooling means (35) based on a result of detection by the first temperature detection means (51, 51', 60, 80).
9. The laser treatment apparatus according to claim 8 further including:
- contact detection means (15) for detecting the contact state of the contact face (42) of the contact member (40) with respect to the affected part;
- second temperature detection means (31) for detecting a temperature of the contact member (40) or the cooling means (35); and
- wherein when the contact detection means (15) detects that the contact face (42) is apart from both of the affected part and the periphery thereof, the temperature control means (15) controls cooling operations of the cooling means (35) based on a result of detection by the second temperature detection means (31).
10. The laser treatment apparatus according to claim 9, wherein the contact detection means (15) detects the contact state of the contact face (42) of the contact member (40) based on the result of detection by the first temperature detection means (51, 51', 60, 80).
11. The laser treatment apparatus according to any one of claims 1 to 10 further including a support member (35) for supporting the laser irradiation unit (20) on the affected part, the support member (35) including the contact member (40).
12. The laser treatment apparatus according to any one of claims 1 to 11 further including a laser transmission member (42, 44) made of material that is good in thermal conductivity and transmittable to the laser beam, wherein the contact face (42) includes at least a

face of the laser transmission member.

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FIG.1

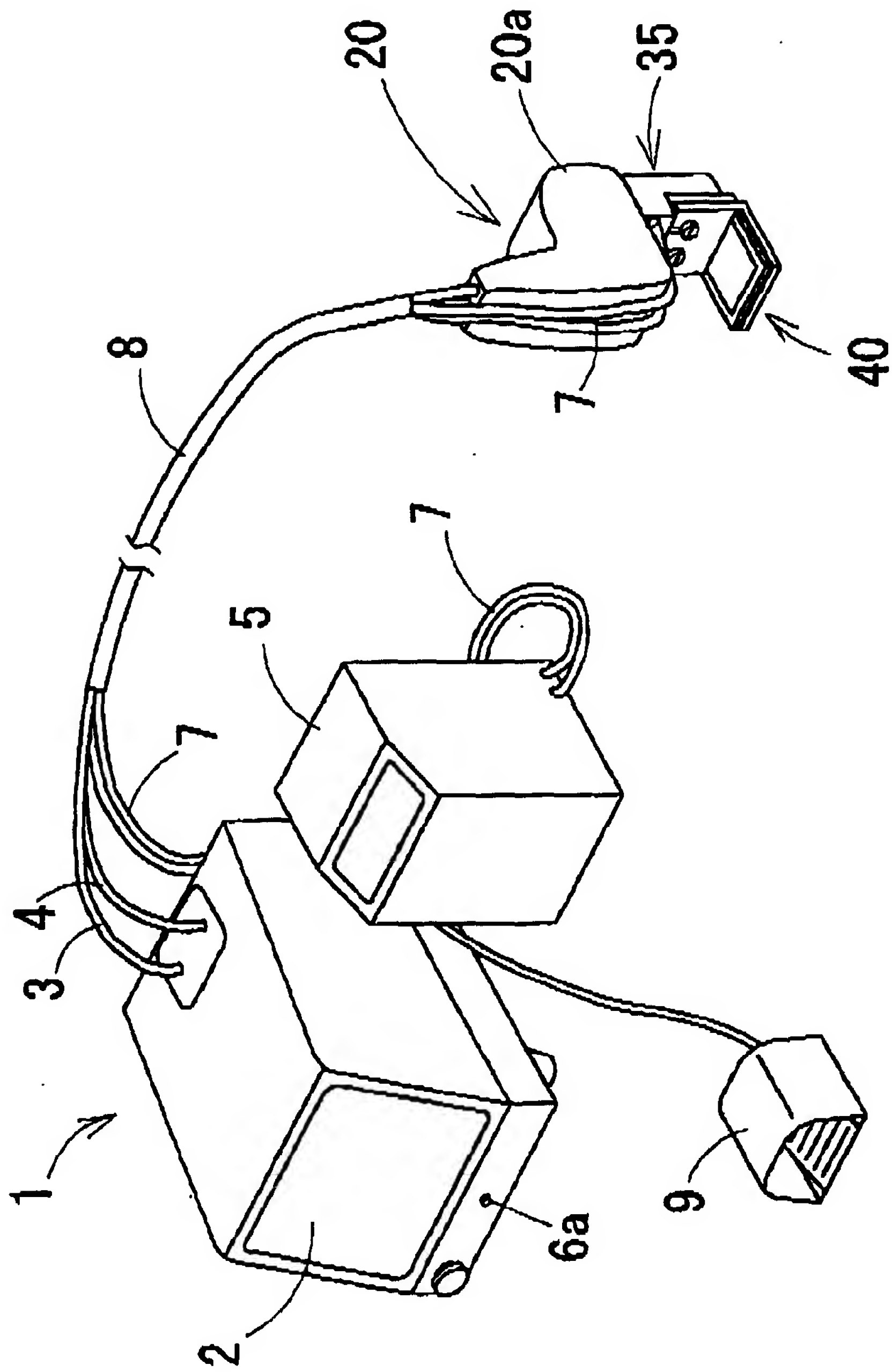


FIG.2

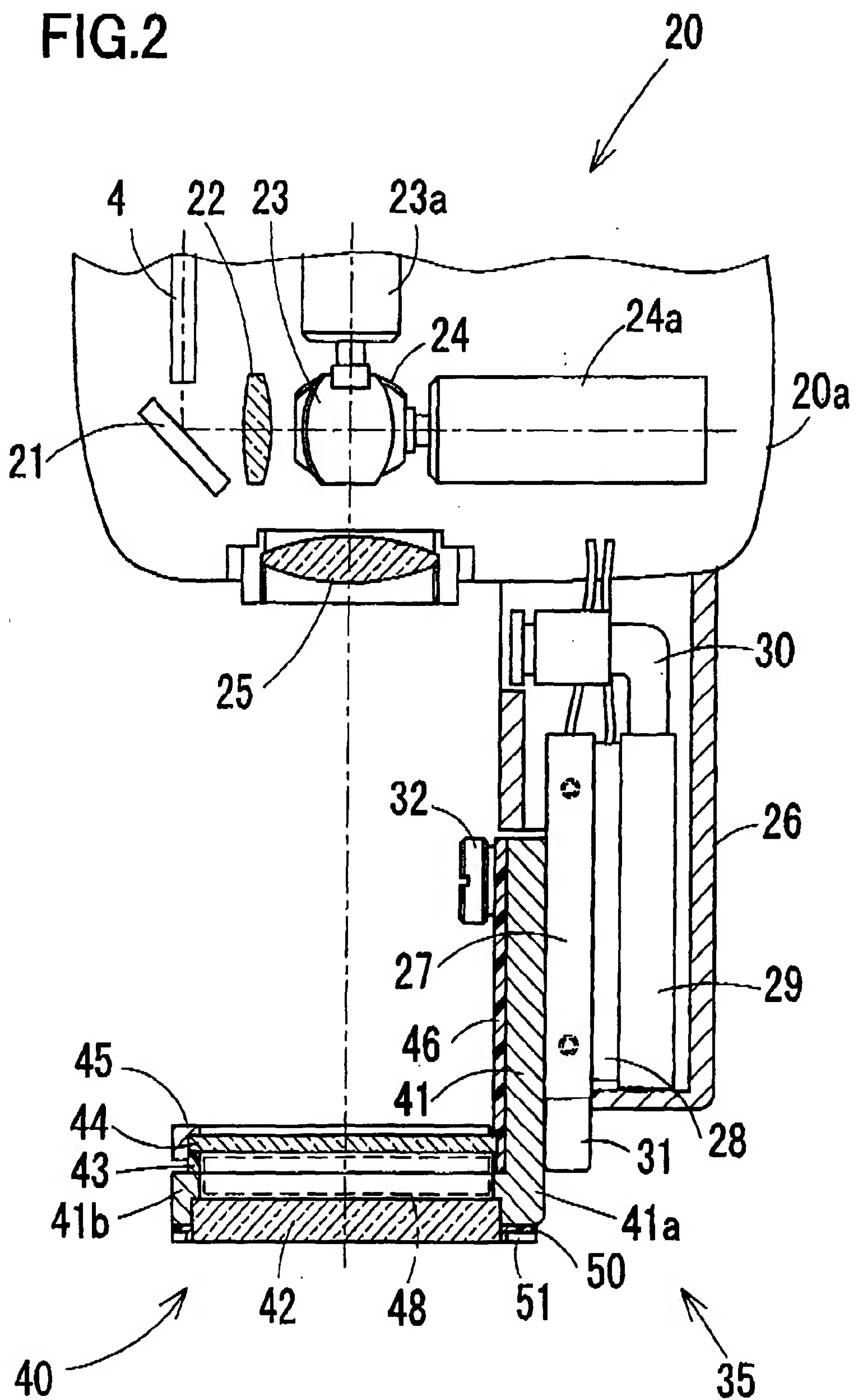


FIG.3

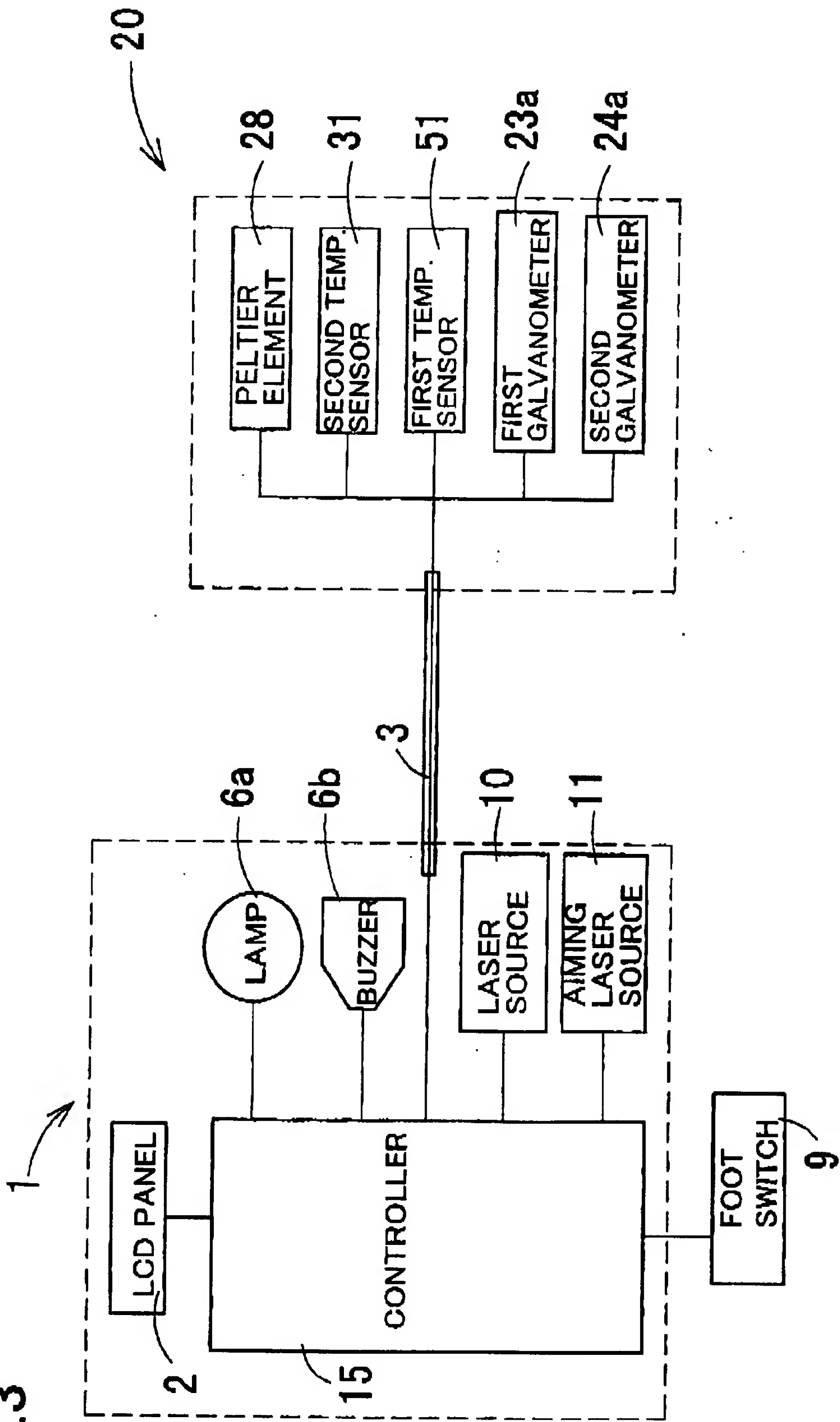


FIG.4A

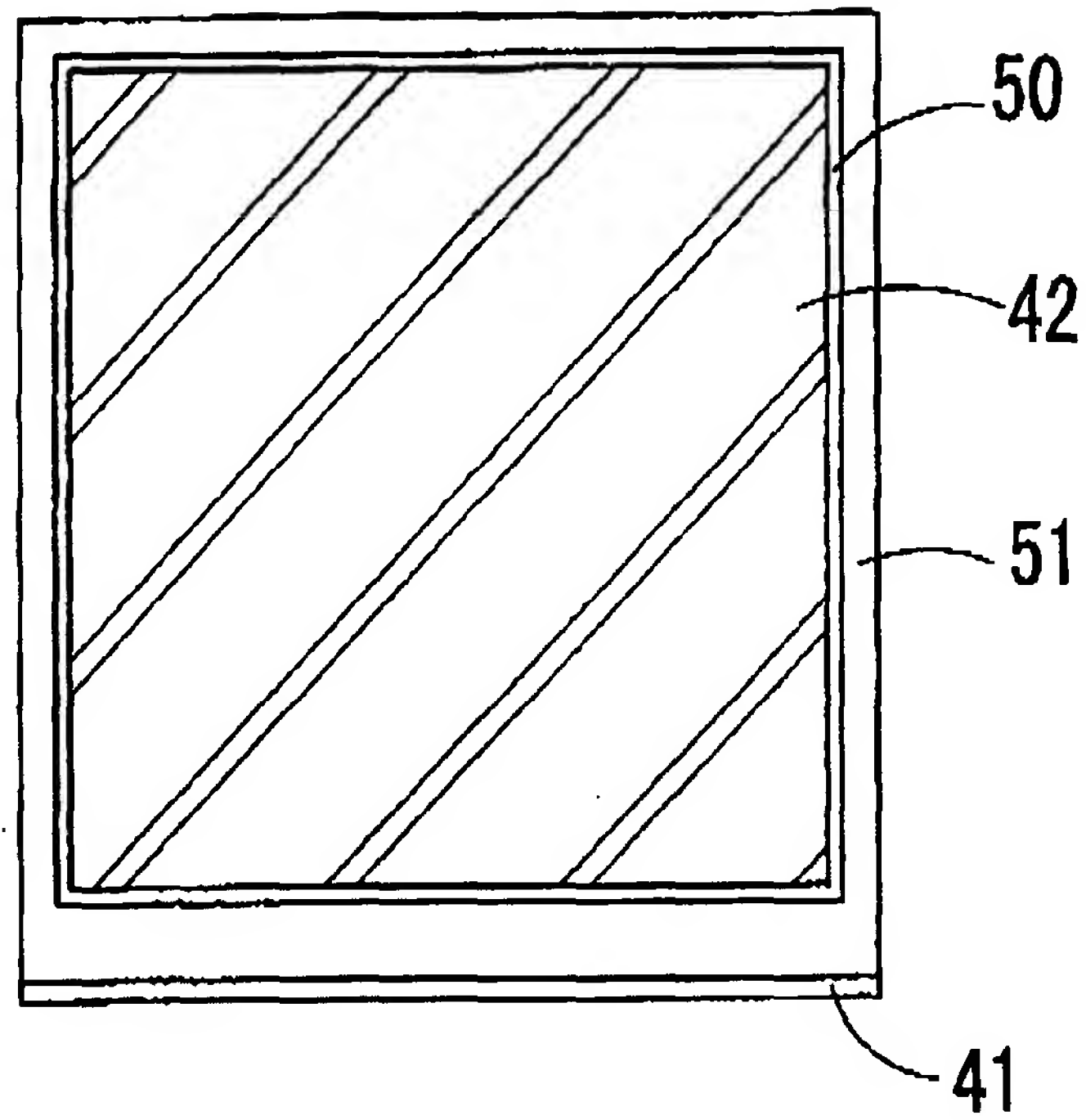


FIG.4B

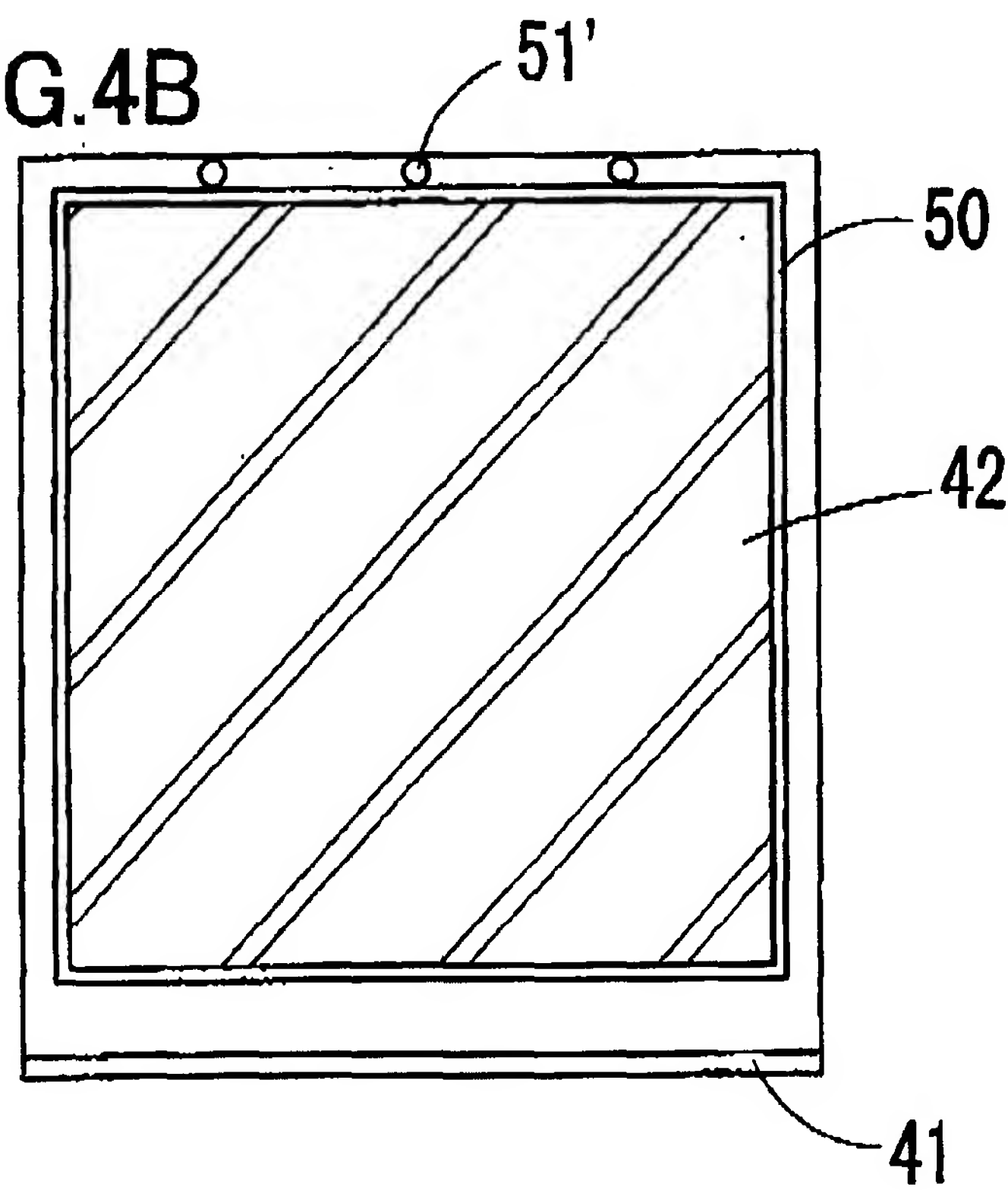


FIG.5

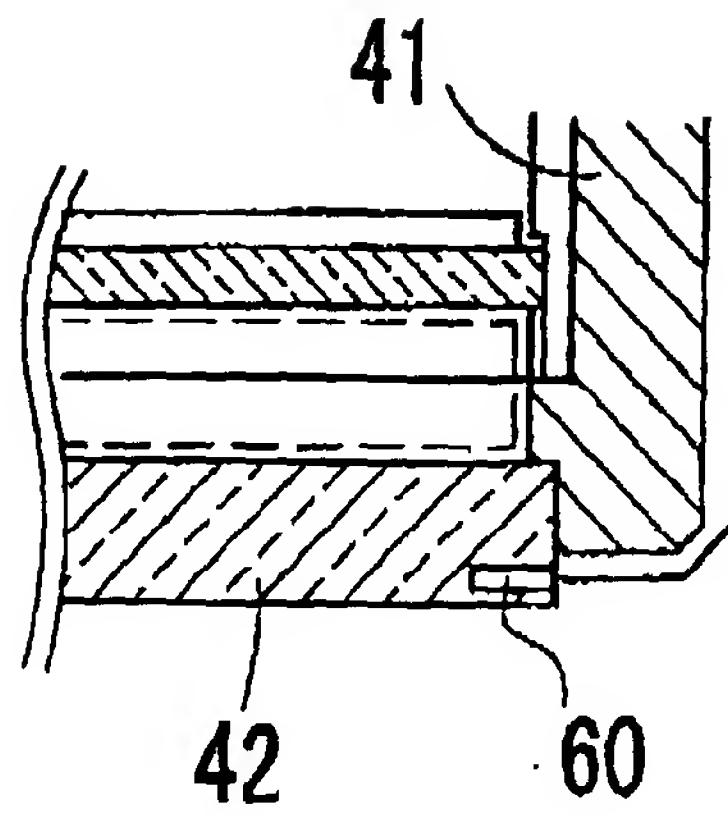


FIG.6

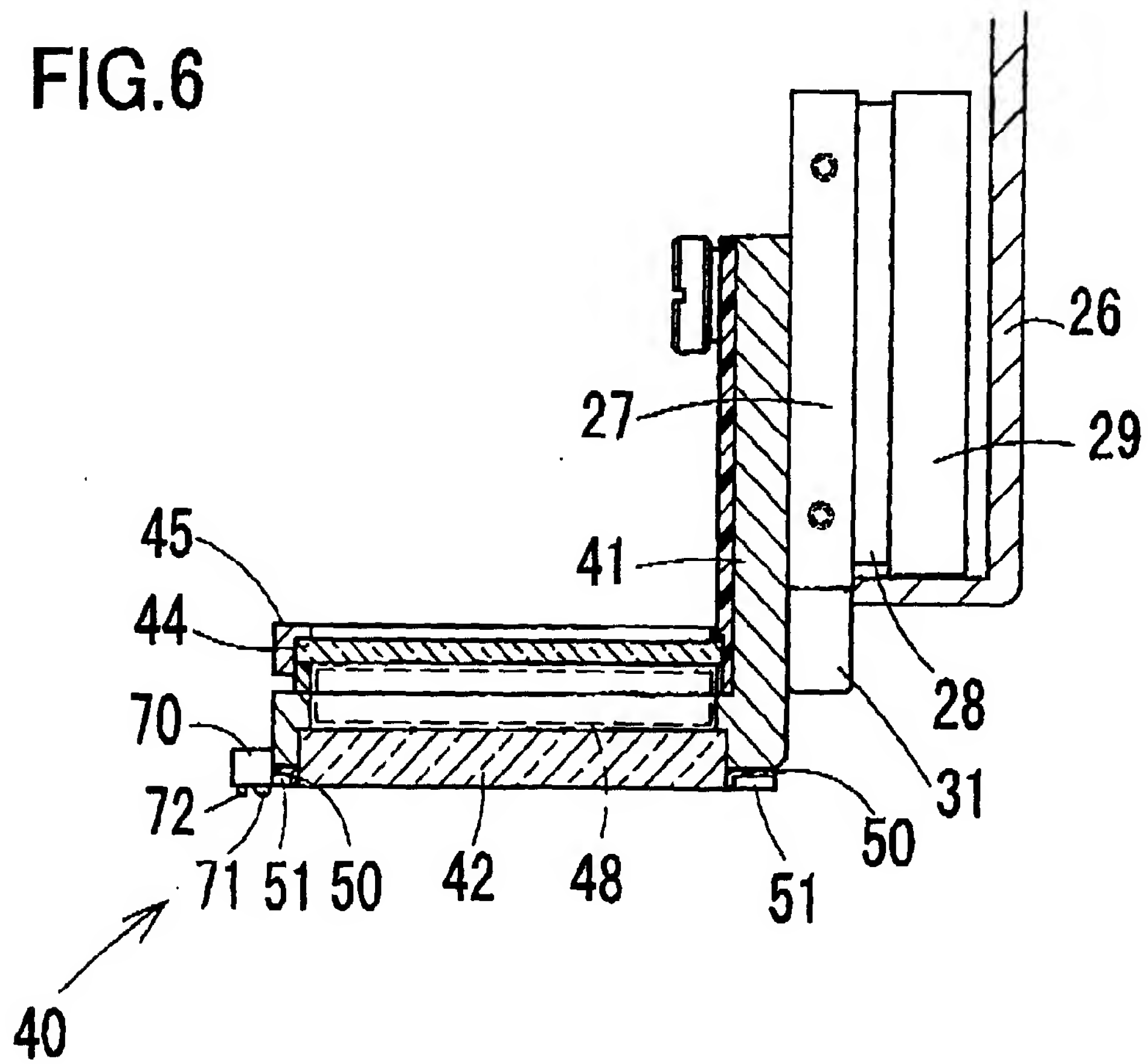


FIG.7A

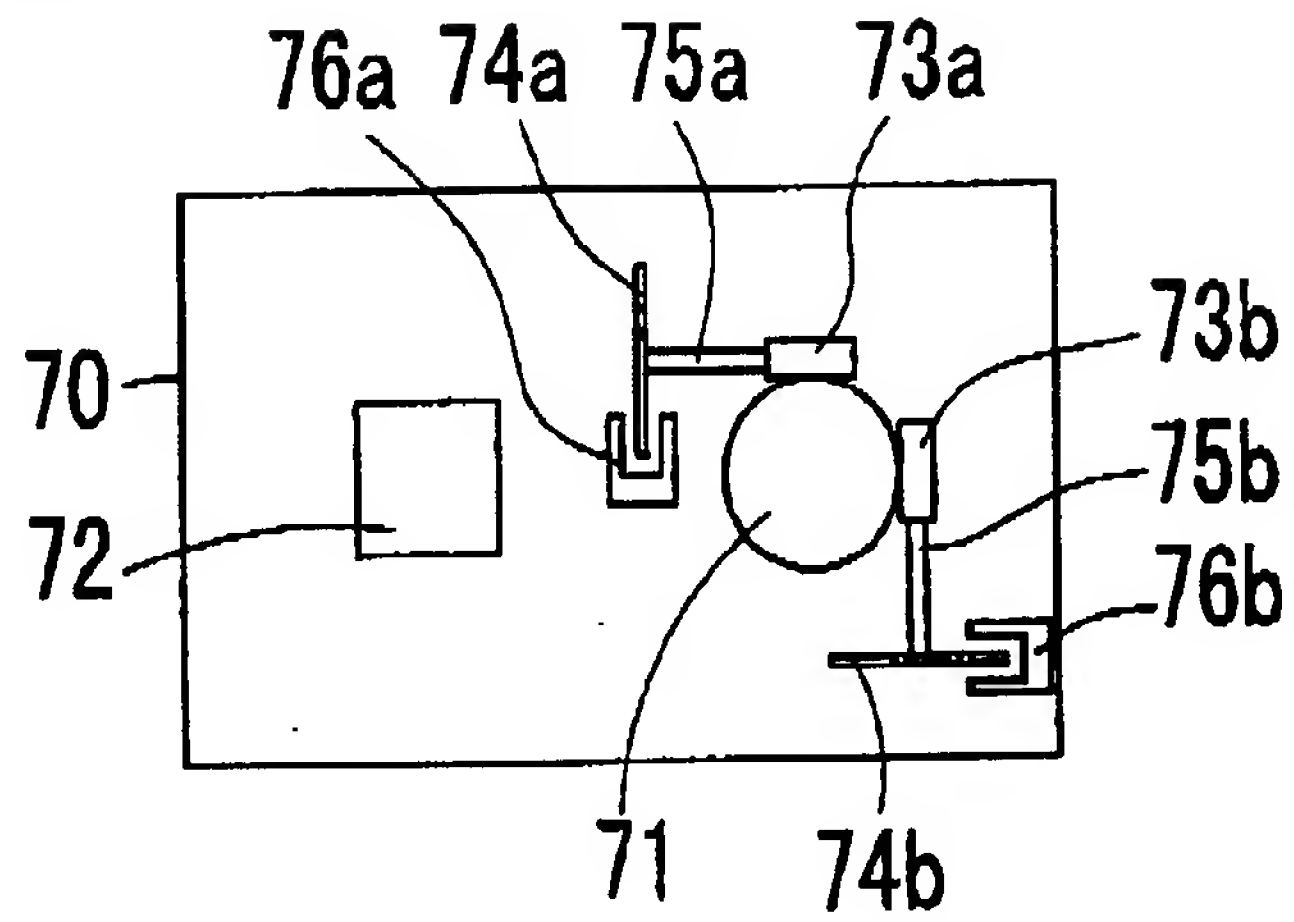


FIG.7B

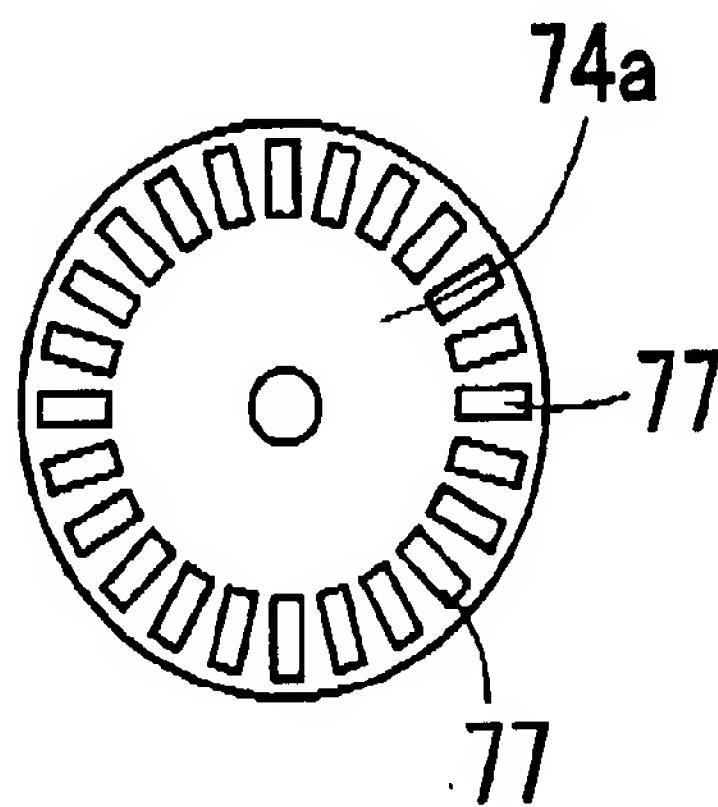


FIG.8

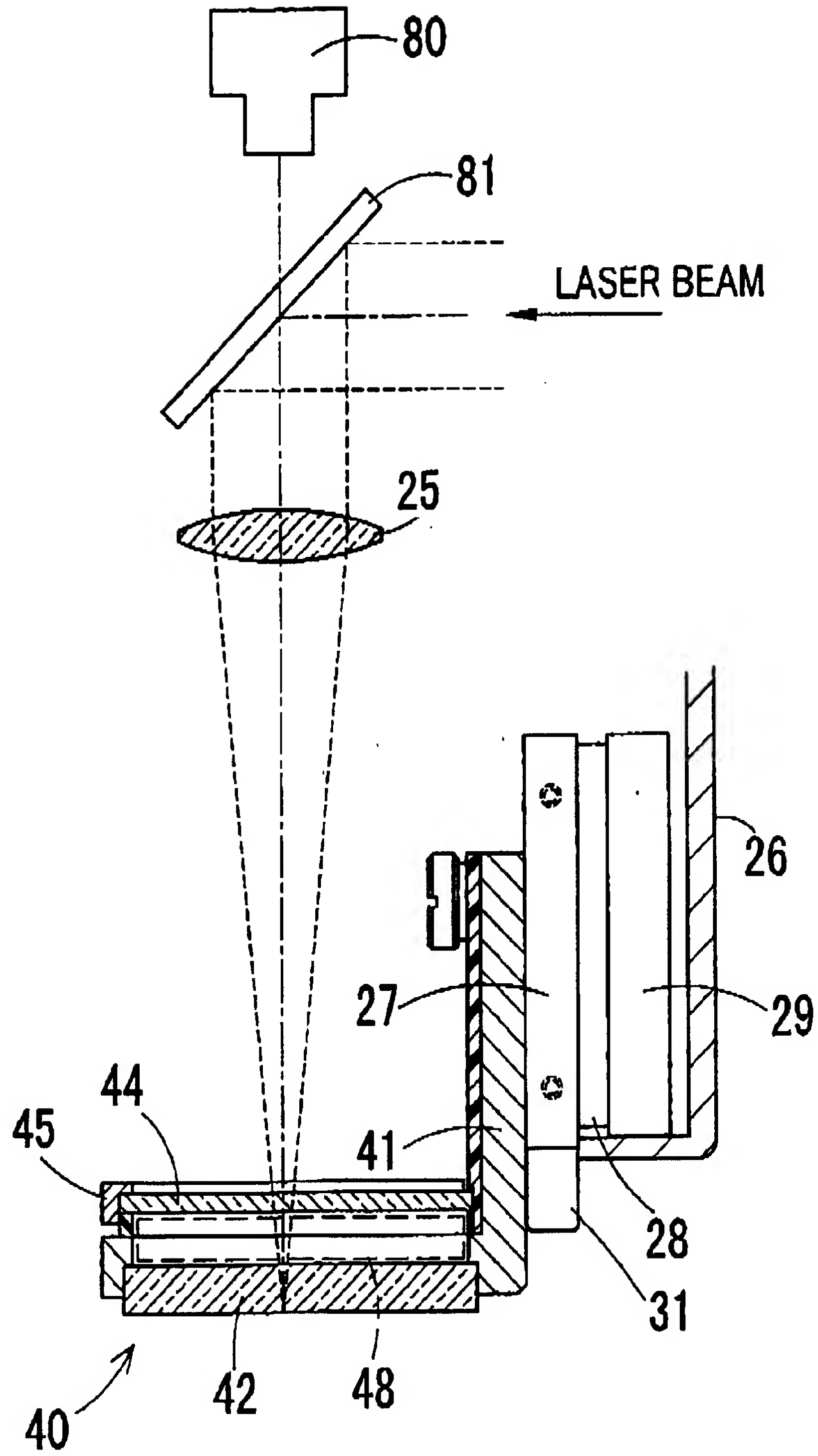
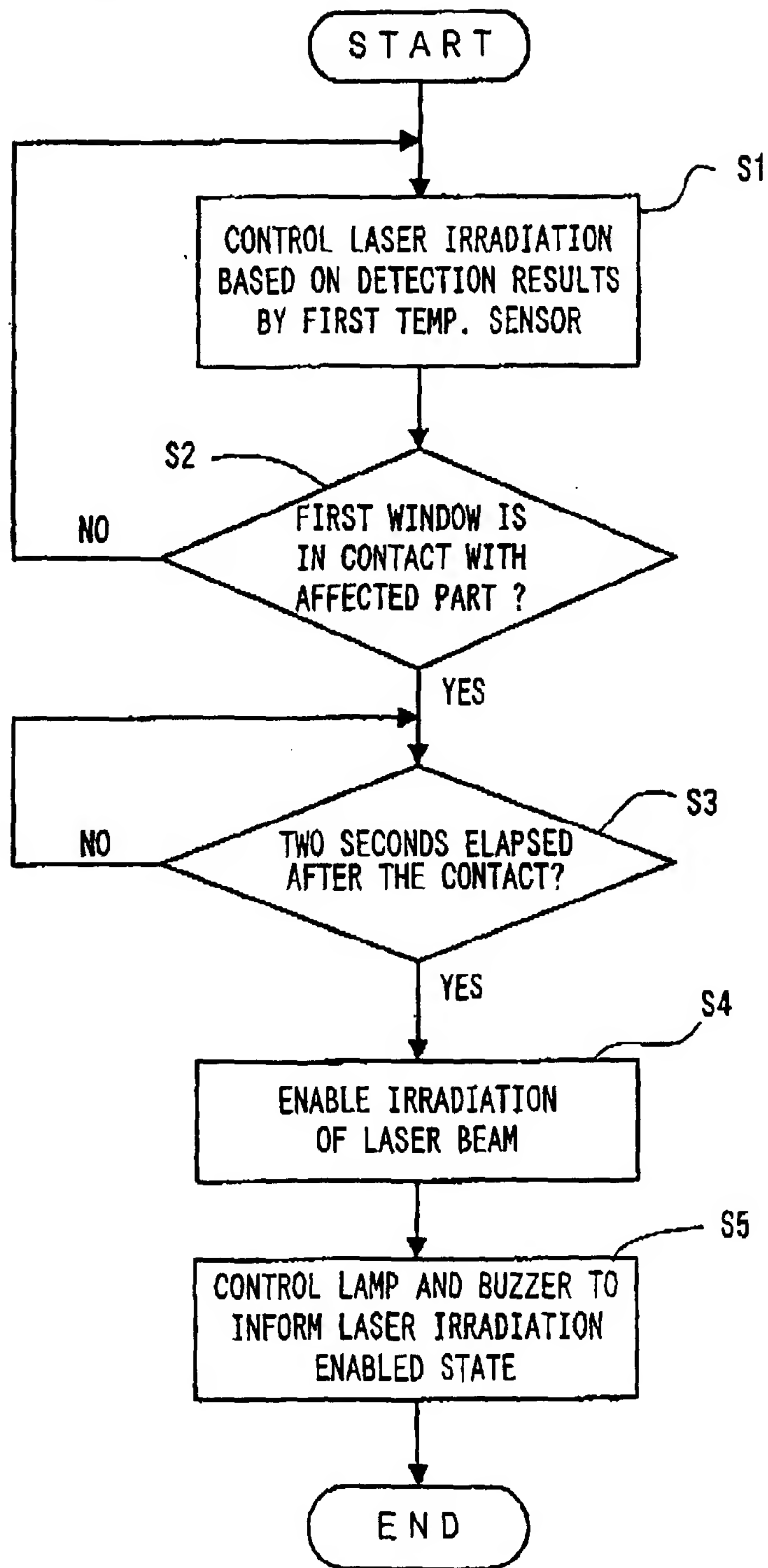


FIG. 9





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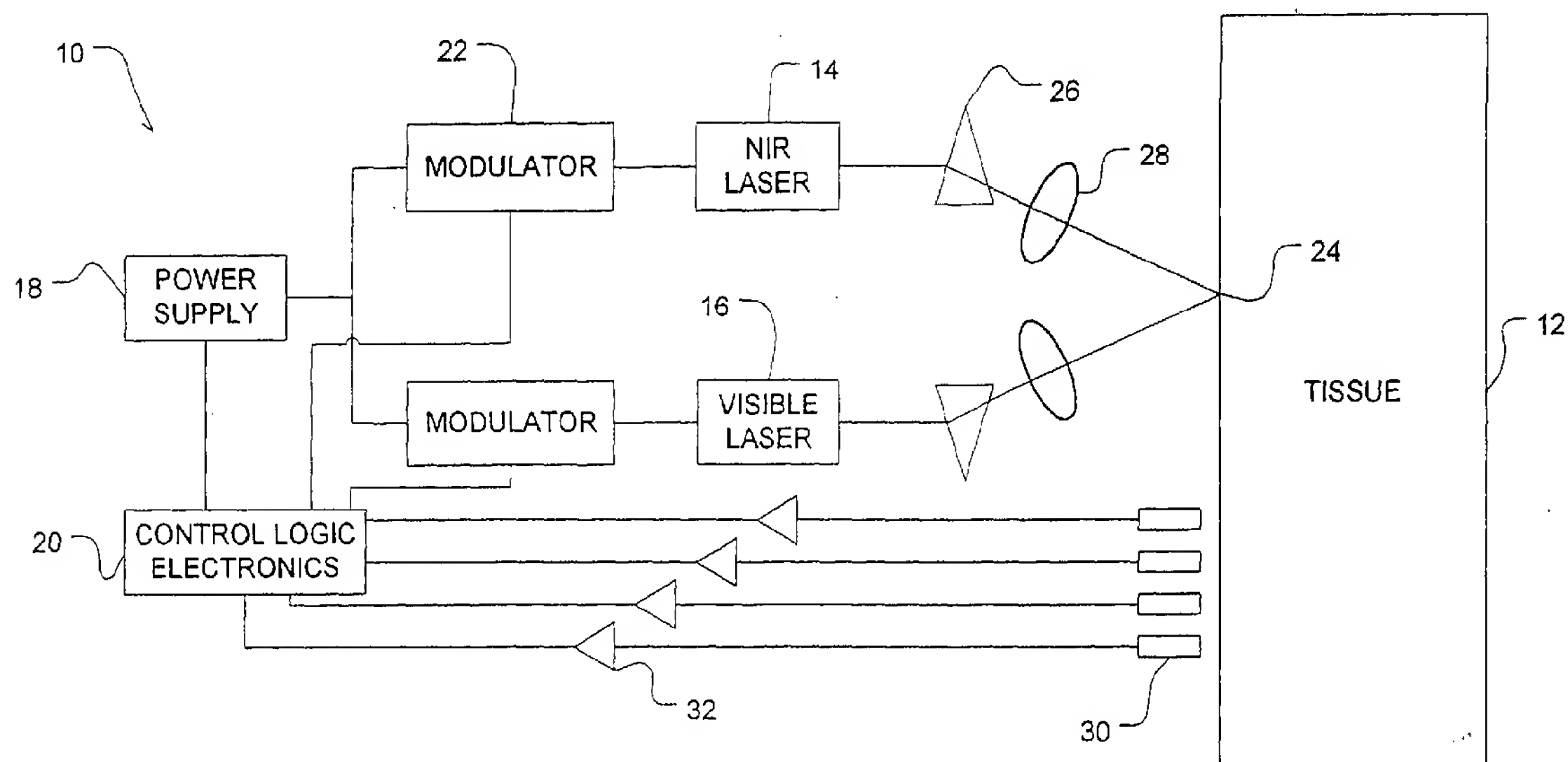
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(54) **Laser apparatus and method of use thereof**

(57) A method is provided for treating a patient having a disorder, wherein the method includes irradiating a tissue surface of the patient with at least one laser beam, automatically monitoring the tissue, and automatically controlling the at least one laser beam to adjust and/or terminate the treatment in a therapeutically effective manner. The method noninvasively determines

in real-time the irradiance and/or radiant exposure of a target tissue at a predetermined depth below the tissue surface by detecting the radial dependence of light remitted from the tissue surface. Preferably, the method employs a near-infrared light laser beam and a visible laser light beam in combination. An apparatus for performing the method is also provided.

FIG. 1



Description

[0001] This invention relates to methods and devices for treating soft tissue disorders, and more particularly to laser therapeutic methods and devices.

[0002] Therapeutic lasers are useful in the treatment of certain types of tissue disorders. See, e.g. US Patents Nos. 4,215,694 to Isakov et al, 4,640,283 to Sawa et al, 4,671,285 to Walker, 4,724,835 to Liss et al, 4,930,504 to Diamantopoulos et al, 4,930,505 to Hatje, 4,966,144 to Rochkind et al, 5,092,581 to Kaga et al, 5,051,823 to Cooper et al, 5,150,704 to Tatebayashi et al, 5,320,619 to Badawi, 5,344,434 to Talmore, 5,409,482 to Diamantopoulos, 5,445,146 to Bellinger, 5,445,608 to Chen, 5,464,436 to Smith, 5,514,168 to Friedman, 5,616,140 to Prescott, 5,649,924 to Everett et al, 5,755,752 to Segal.

[0003] Laser therapy (i.e. Low Level Laser Therapy or LLLT) generally requires the injured tissue to be exposed directly to the laser light for predetermined intervals of time. Exposure to laser light not only lessens the pain associated with certain disorders, but actually speeds the healing of the treated tissues. The wavelength of the laser light, the intensity of the laser light and the exposure time are important factors when selecting a specific treatment protocol for a specific disorder.

[0004] The wavelength of the laser light affects its ability to penetrate through overlaying tissues, such as skin, to reach the tissues and molecules of interest. For example, red light is attenuated by most tissues ($1/e^2$ attenuation), and thus the penetration depth is less than 1 cm into such tissues, whereas near-infrared (NIR) light is less attenuated by most tissues, and thus can penetrate more than 1 cm into such tissues.

[0005] The wavelength of the laser light also affects its ability to promote biological pathways for healing injured tissues. For example, the quantum energy of near-infrared photons is small, and thus near-infrared photons have a relatively low potential to electronically exciting biomolecules. On the other hand, the quantum energy of red wavelength photons is sufficient to achieve electronic excitation of biomolecules, potentially promoting direct photochemical and photobiological effects in target tissues.

[0006] The precise nature of the molecular events caused by narrow bandwidth red and near-infrared light irradiation is still under investigation. However, clinical evidence suggests that biostimulation using red light and biostimulation using near-infrared light each promotes wound healing and/or relieves the symptoms of rheumatoid arthritis. See, e.g. Mester et al, "Wound Healing", 1 Laser Therapy 7-15 (1989), and Asada et al, "Diode Laser Therapy for Rheumatoid Arthritis: A Clinical Evaluation of 102 Joints Treated with Low Reactive-Level Laser Therapy (LLLT) 1 Laser Therapy 147-152 (1989).

[0007] The intensity of the laser light used to treat an

injury is another factor in its effectiveness. Applying a therapeutically insufficient intensity of laser light to an injury has no desirable effects, but applying excess intensity can cause undesirable heating, burning and even vaporization of tissue.

[0008] The total exposure time is also an important factor in laser therapy, as combined with irradiance it determines the total deposited energy. If an injury is not exposed to laser light for an appropriate interval of time, insufficient healing may result. Excess exposure to laser light can injure the target tissues.

[0009] As the target tissue for laser therapy is typically subcutaneous, and the factors controlling the penetrability of a patient's skin (e.g. thickness, fat content, colour, etc.) vary from patient to patient, it has been difficult to employ one ideal protocol for all patients. That is, the target tissue is typically located at a certain depth " Z_0 " below the surface, and the energy delivered to depth " Z_0 " has been difficult to monitor and control. Protocols can be manually adjusted to the particular patient, but this adds complexity to the treatment, and more heavily relies on the proper training of medical personnel.

[0010] A variety of laser systems in the laser therapy and laser surgery arts have been proposed that intelligently control laser beam intensity and duration using target monitoring and feedback (real-time and otherwise). See, e.g. US Patents Nos. 5,657,760 to Ying, 5,423,801 to Marshall, 5,354,323 to Whitebook, 5,154,707 to Rink et al, 5,050,597 to Daikuzono, 4,973,848 to Kolobanov et al, and 4,644,948 to Lang et al.

[0011] According to one aspect of the invention there is provided a method for irradiating tissue with a near-infrared laser light having a first therapeutically effective intensity and with a visible laser light having a second therapeutically effective intensity; automatically monitoring said irradiated tissue; and automatically terminating said irradiating when said monitoring indicates that said near-infrared laser light and said visible laser light have been applied to said tissue for a duration therapeutically effective to treat said disorder.

[0012] According to another aspect of the invention, there is provided a laser apparatus adapted to perform the method of the invention, said laser apparatus comprising: a near-infrared light laser; a visible light laser; a power supply in electrical communication with said lasers; waveguides for guiding beams from said lasers to a common focal point on a surface of a target tissue; detectors adapted to detect radiation remitted from said target surface along a radius originating at said common focal point; and control logic electronics adapted to automatically adjust an output of said lasers based on said remitted radiation detected by said detectors.

[0013] The invention also provides a method for administering a predetermined dose of radiation to a distal target tissue, said method comprising: irradiating a proximal tissue adjacent said distal target tissue with at least one laser light which penetrates through said proximal

tissue to administer radiation to said distal target tissue; automatically monitoring said proximal tissue to determine whether to terminate said irradiating, said monitoring comprising detecting a radial dependence of a diffuse reflectance from a surface of said proximal tissue of said at least one laser light; and automatically terminating said irradiating when said monitoring indicates that said predetermined dose of laser light has been applied to said distal target tissue.

[0014] According to a still further aspect of the invention, there is provided a laser apparatus adapted to perform the method of the invention which comprises: at least one laser; a power supply in electrical communication with said at least one laser; at least one detector adapted to detect radiation remitted from two points on said target surface along a radius originating at a focal point of said at least one laser on said proximal tissue; and control logic electronics adapted to automatically adjust an output of said at least one laser based on said remitted radiation detected by said at least one detector.

[0015] The preferred apparatus of the invention is characterised by means for irradiating tissue with a near-infrared laser light having a first therapeutically effected intensity and with a visible laser light having a second therapeutically effected intensity; means for automatically monitoring said irradiated tissue and automatically terminating said irradiating when said monitoring means indicates that said near-infrared laser light and said visible laser light have been applied to said tissue in amounts therapeutically effective to treat said disorder.

[0016] The monitoring means preferably noninvasively determines the subsurface intensity of at least one of said near-infrared laser light and said visible laser light.

[0017] Preferably, said monitoring means analyzes a radial dependence of a diffuse reflectance from said tissue of at least one of said near-infrared laser light and said visible laser light. In the preferred embodiment, said diffuse reflectance is detected from at least two detection points on a surface of said tissue, said two detection points being at separate positions along a radius originating at a surface focal point of said laser lights.

[0018] The apparatus of the invention preferably also includes means for automatically adjusting the intensity of at least one of said near-infrared laser light and said visible laser light in response to information obtained by said monitoring means.

[0019] Preferably, the near-infrared laser light has a wavelength of 750 to 1000nm and the visible laser light has a wavelength of 450 to 749nm.

[0020] Preferably, the near-infrared laser light and the visible laser light has a peak intensity of 0 to 2000 watts/cm².

[0021] The apparatus preferably also includes means to pulse the near-infrared laser light and said visible laser light. In the preferred embodiment, said means pulse the near-infrared laser light at a first frequency and said visible laser light at a second frequency different from

said first frequency, the signals of said near-infrared laser light and said visible laser light being detected by a common sensor and filtered by frequency.

[0022] Preferably, said irradiating is terminated when said monitoring means indicates that at least one of said near-infrared laser light and said visible laser light has penetrated to a sub-surface region of said tissue in an amount therapeutically effective to treat said disorder.

[0023] In a preferred apparatus for administering a predetermined dose of radiation to a distal target tissue, there are provided means for irradiating proximal tissue adjacent said distal target tissue with at least one laser light which penetrates through said proximal tissue to administer radiation to said distal target tissue; means for automatically monitoring said proximal tissue to determine whether to terminate said irradiating, monitoring means for detecting a radial dependence of a diffuse reflectance from a surface of said proximal tissue of said at least one laser light; and means for automatically terminating said irradiating when said monitoring indicates that said predetermined dose of laser light has been applied to said distal target tissue.

[0024] Preferably, said diffuse reflectance is detected from at least two detection points on said surface of said proximal tissue, said two detection points being at separate positions along a radius originating at a surface focal point of said at least one laser light.

[0025] Preferably, the apparatus also includes means for automatically adjusting the intensity of said at least one laser light.

[0026] Embodiments of the invention will now be described, by way of example only, with reference to the following drawings in which like reference numerals designate like elements and wherein:

Figure 1 is a schematic block diagram of an embodiment of the invention;

Figure 2 is a flow diagram of a process executed by the control logic electronics of the embodiment of Figure 1;

Figure 3 is a schematic block diagram of another embodiment of the invention; and

Figure 4 is a cross-sectional view through line 4-4 of Figure 3.

[0027] Figure 1 shows a general schematic diagram for a preferred laser apparatus 10 of the invention. Laser apparatus 10 is generally useful for treating, e.g. tissue disorders (as used herein, the expression "tissue disorders" denotes disorders associated with the tissues regardless of where such disorders originate or are manifested), such as tissue 12 shown in the figures. Laser apparatus 10 enables a method for treating tissue disorders to at least alleviate certain symptoms of the disorders, such as e.g. pain.

[0028] The laser apparatus 10 of Fig. 1 comprises one near-infrared (NIR) light laser 14 and one visible light laser 16. The lasers 14 and 16 are energized by a power

supply 18. The power output from power supply 18 is controlled by control logic electronics 20, either alone or in combination with modulators 22, as shown in the figures. Laser apparatus 10 is thereby adapted to control power density (i.e., irradiance in watts/cm²) delivered to the target tissue 12, as well as the total delivered energy dosage (i.e., radiant exposure in joules/cm²) of radiation.

[0029] In embodiments, laser apparatus 10 is adapted to selectively produce pulses of laser light at a frequency of between 0 to 50,000 and preferably 0 to 30,000 pulses per minute, each pulse preferably having a peak intensity of between 0 and 2000 watts/cm².

[0030] NIR laser 14 is adapted to selectively produce laser light having a near-infrared wavelength and the frequency and intensity discussed above. Preferably, NIR laser 14 emits a beam having a wavelength of about 750 to about 1000 nm, more preferably about 900 to about 930 nm, most preferably about 905 nm.

[0031] Visible light laser 16 is adapted to selectively produce laser light having a wavelength in the visible light range and the frequency and intensity discussed above. Preferably, visible light laser 16 emits a beam having a wavelength of about 450 to about 749 nm, more preferably about 620 to about 670 nm, most preferably about 660 nm.

[0032] Lasers 14 and 16 can be the same or different types of laser, and in certain embodiments, lasers 14 and 16 can be merged into a single laser adapted to selectively produce coherent energy at wavelengths within the visible and near-infrared regions of the electromagnetic spectrum. Suitable lasers 14 and 16 according to the invention, include, e.g., noble gas lasers (e.g., argon lasers, helium-neon lasers, etc.), diode lasers and tunable dye lasers.

[0033] Each of the beams emitted from lasers 14 and 16 is preferably directed at a common focal point 24 on tissue 12, using a waveguide, such as a converging prism 26 and focusing lens 28, as shown in Fig. 1. Other suitable waveguides include, e.g., lenses having different configurations, a hollow metallic waveguide, a hollow dielectric waveguide, and/or an optical fiber (as discussed below and shown in Fig. 3). Suitable waveguides are also suggested in U.S. Patent No. 4,963,143 to Pinnow.

[0034] In embodiments, the laser beams converge prior to focal point 24, to yield coaxial beams comprising coherent radiation at a visible wavelength and coherent radiation at a near-infrared wavelength. The coaxial beams are preferable to other beam conformations, as the beams penetrate to subsurface regions directly below focal point 24, rather than subsurface regions that are not centered below focal point 24.

[0035] In embodiments wherein both beams are emitted by the same laser, the near-infrared beam and the visible beam can be alternately pulsed at focal point 24 to produce a desired effect.

[0036] Although dual wavelength laser irradiation is a

preferred embodiment of the invention, irradiation with a single wavelength or with more than two wavelengths of coherent radiation also forms a part of this invention, preferably in conjunction with the automated control system described immediately below.

[0037] In preferred embodiments, the invention includes an automated control system, comprising feedback-controlled irradiation of target tissues. A preferred laser apparatus according to the invention non-invasively detects, in real-time, the radiant exposure and/or irradiance of radiated energy within the tissue beneath the laser focal point on the surface of the target tissue. In particular, the diffuse reflectance of the visible and/or near-infrared light is detected, thus enabling the determination of the irradiance at a predetermined depth, and in conjunction with the exposure time, the actual radiant exposure at the predetermined depth.

[0038] Thus, detectors 30 are used to monitor the energy characteristics of tissue 12. Preferably, detectors 30 are positioned along a radius originating at focal point 24 to detect the diffuse radiation emitted from tissue 12. At least two detectors 30 are positioned at different points along the radius, and preferably four detectors 30 are so positioned, as shown in the figures. In embodiments, a single detector can be moved along a radius to measure the radial dependence of the diffuse radiation emitted from tissue 12. Detectors 30 suitable for use in the invention include, e.g., optical fibers terminating into fast silicon detectors, gallium arsenide detectors and indium phosphide detectors.

[0039] The signals from detectors 30 are preferably amplified by amplifiers 32 before being reported to control logic electronics 20.

[0040] Control logic electronics 20 include a processor (not shown), which executes modules 34-44 (Fig. 2). The processor in control logic electronics 20 detect (in module 34) when user activates a trigger, switch or button (not shown) of laser apparatus 10. When the trigger is depressed, the processor executes module 36 and then module 37. Until the trigger is depressed, the processor continues to execute module 34.

[0041] In module 36, control logic electronics 20 actuate lasers 14 and 16, and in module 37, control logic electronics 20 determine the intensity of the radiation at a predetermined depth, Z_0 , within tissue 12 below focal point 24, and thus the radiant exposure and irradiance at Z_0 , with known exposure time. This determination is preferably made using an analysis of the radial dependence of diffuse remitted radiation detected by detectors 30 positioned along a radius originating at focal point 24.

[0042] The attenuation of the optical radiation from tissue 12 as a function of depth Z is related to the absorption and scattering properties of the tissue, resulting in large variations in the depth distribution of the power/energy. Using a theoretical model of light propagation in turbid media (e.g., tissue 12), such as Diffusion Theory, it can be shown that the radial dependence of the diffuse remitted radiation is also a function of the same optical

properties. See, e.g., Farrell et al., "A diffusion theory model of spatially resolved, steady-state diffuse reflectance for the non-invasive determination of tissue optical properties in vivo," 19(4) Med. Phys. 879-88 (1992), and Weersink et al., "Accuracy of non-invasive in vivo measurements of photosensitizer uptake based on a diffusion model of reflectance spectroscopy," 66(3) Photochem. Photobiol. 326-35 (1997). Hence, the radial dependence of the diffuse reflected radiation contains information regarding subsurface radiation.

[0043] Control logic electronics 20 determine the radial dependence of the diffuse reflected radiation from the intensity of the signal relayed to it from each detector 30, and the radial distance of each detector 30 from focal point 24. The radial dependence is then used to estimate the depth dependence of intensity (i.e., the attenuation of intensity as a function of depth) in the tissue being treated. For example, the radial dependence can be used to generate a curve or formula for a curve, which can in turn be used to select a depth dependence curve or formula from a look-up table. In any event, the intensity (or irradiance) of radiation at target depth Z_0 is determined from the depth dependence curve or formula, and the radiant exposure at target depth Z_0 is determined by, e.g., integration.

[0044] After executing module 37, the processor then executes module 38. In module 38, the processor compares the value of the radiant exposure at Z_0 to a predetermined radiant exposure value. If the detected radiant exposure is greater than or equal to the predetermined radiant exposure value (which is preferably a therapeutically optimum value), module 40 is executed and lasers 14 and 16 are disabled. Lasers 14 and 16 can be disabled in a variety of ways, including interrupting the supply of power to them from power supply 18, modulating the power supply through modulators 22 to the lasers, and/or modulating the beam exiting lasers 14 and 16 using downstream laser modulators, such as shutters (not shown).

[0045] If the detected radiant exposure at Z_0 is less than the predetermined radiant exposure, module 42 is executed. In module 42, the processor compares the value of the irradiance at Z_0 with a predetermined irradiance (which is preferably a therapeutically optimum value). If the detected irradiance at Z_0 is equal to the predetermined irradiance, module 37 is executed again. If the detected irradiance is not equal to the predetermined irradiance, module 44 is executed. Module 44 adjusts the intensity of the appropriate laser(s) in accordance with the discrepancy between the detected irradiance and the predetermined irradiance, and then executes module 37 again.

[0046] Control logic electronics 20 are preferably adapted to irradiate tissue 12 with radiation having a preselected peak intensity, average intensity and duration. Preferably, control logic electronics 20 are further provided with sufficient computer memory to store a series of treatment protocols for different ailments and/or

patients, eliminating the need to reprogram the device after each treatment.

[0047] Modulators 22 are included to provide the capability of modulating the output from lasers 14 and 16.

5 Modulation is preferably used for two purposes. First, modulation of laser output is used to control the radiant exposure and irradiance in tissue 12. Second, NIR laser 14 is preferably modulated at a different frequency than visible light laser 16 to enable frequency-filtered detection (e.g., using Fourier transform analysis). The remitted intensity of radiation having a first wavelength modulated by a first carrier frequency, can be distinguished from the remitted intensity of radiation having a second wavelength modulated by a second carrier frequency, by performing lock-in detection at the two different carry frequencies. The attenuation of the two respective wavelengths in the tissue of choice can be quantified by measuring the demodulation of the AC signal and the phase shift compared to the source. The intensity of the radiation emitted from tissue 12 can thus be determined at each of the two frequencies using common detectors.

[0048] Of course, other signal filtration systems are also suitable for use in the invention, including, e.g., optical filters and time-resolved filtration systems. Alternatively, a variety of narrow wavelength-specific detectors can be used in the apparatus of the invention to independently detect reflectance of a plurality of wavelengths.

[0049] Modulators 20 can be positioned before and/or after lasers 14 and 16. Suitable modulators 20 according to the invention include, e.g., frequency controlled driver circuits or acoustooptic modulators. Modulators 20 need not all be of the same type. For example, the modulators positioned before the lasers can be electrical devices adapted to control the amplitude and/or pulse timing of the laser beams emitted by the lasers, while the modulators after the lasers can be mechanical and/or optical shutters.

[0050] Fig. 3 shows an alternative embodiment of the invention, wherein focusing lenses 28 and optical fibers 46 act as waveguides directing the near-infrared laser beam and the visible laser beam through an applicator 48 and into tissue 12. This embodiment of the laser apparatus of the invention is particularly well-suited to treating tissue located in confined areas of the body, such as inside a body cavity, such as the mouth. Applicator 48 is applied to (or brought into close proximity with) tissue 12. Detectors 30 are preferably housed in applicator 48 for ease and precision of use.

50 **[0051]** In embodiments, applicator 48 is specifically adapted for its intended use. Interchangeable applicators 48 can be provided to customize the functionality of a universally adaptable (or at least widely adaptable) apparatus 10. Thus, for example, applicator 48 can be relatively small for conducting treatment within confined spaces, such as the mouth and endoscopic surgical fields. Applicator 48 can include "floating" detectors 30 and/or "floating" waveguide ends, which maintain close

contact between applicator 48 and tissue 12 despite surface irregularities of the tissue or tissue contours (in a manner similar to the spring-loaded laser heads disclosed in U.S. Patent No. 5,150,704 to Tatebayashi et al.).

[0052] Fig. 4 is a cross-sectional view through line 4-4 of Fig. 3, which demonstrates an example of the radial positioning of detectors 30 preferably used to determine the radial dependence of the diffuse reflected light.

[0053] In addition to targeting treatment to a single depth, the invention encompasses targeting treatment to a plurality of different depths within a tissue. The multiple depth treatments of the invention can be administered simultaneously, sequentially and/or alternately. For example, a system of the invention can be adapted to target a first depth, reset to target a second depth, reset again to target a third depth, and so forth. In conjunction with the ability of systems of the invention to adjust irradiance, radiant exposure, and wavelength, the ability to target multiple depths provides systems of the invention with superior adaptability to a variety of disorders of a variety of tissues in a variety of patients.

[0054] The invention is additionally suitable for monitoring and controlling thermal laser applications, using feedback from the tissue to control laser dosage.

[0055] The invention will be illustrated in more detail with reference to the following Example, but it should be understood that the present invention is not deemed to be limited thereto.

Example

[0056] A forearm of a patient complaining of pain and stiffness associated with carpal tunnel syndrome is treated with laser beams having wavelengths of 660 nm and 905 nm simultaneously. A laser treatment apparatus of the invention is used to automatically monitor and control the application of the laser light to apply the irradiance and radiant exposure so that a predetermined fluence-rate and fluence are achieved at depth Z. The apparatus is actuated and the diffuse reflectance of the laser light is detected at several points along a radius originating at the focal point of the laser light on the tissue surface.

[0057] To correlate the reflectance as a function of radius $R(\rho)$ with the fluence-rate as a function of depth $\phi(Z)$, a look-up table is generated using diffusion theory (see Farrell et al., supra). For the look-up table, the reflectance, R, at the position of the detectors ($\rho_{x1} \rightarrow \rho_{xn}$) and the fluence-rate at depth ($Z_1 \rightarrow Z_n$) are calculated for the full range of optical absorption and scattering at 660 nm and 905 nm wavelengths, as reported in the literature for human skin.

[0058] In the look-up table, the shape of the reflectance vs. radius @ vs. ρ_x curve is used to select the corresponding fluence-rate vs. depth (ϕ vs. Z) curve. The fluence-rate at depth Z (the parameter of interest) is then obtained through interpolation of the data of ϕ vs. Z.

[0059] The irradiance delivered by the apparatus is adjusted to achieve the predetermined $\phi(Z)$. The adjustment can be limited by reference to predetermined safety limits, such as those published in IEC 825-1, at Table 8 (MPE for skin at 905 nm is about 500 mW and at 660 nm it is about 200 mW).

[0060] While the invention has been described in detail and with reference to specific examples thereof, it will be apparent to one skilled in the art that various changes and modifications can be made therein without departing from the spirit and scope thereof.

Claims

1. A laser apparatus **characterised by** a near-infrared light laser; a visible light laser; a power supply in electrical communication with said lasers; waveguides for guiding beams from said lasers to a common focal point on a surface of a target tissue; detectors adapted to detect radiation remitted from said target surface along a radius originating at said common focal point; and control logic electronics to automatically adjust an output of said lasers based on said remitted radiation detected by said detectors.
2. A method of irradiating tissue characterised by the steps of: irradiating said tissue with a near-infrared laser light having a first therapeutically effective intensity and with a visible laser light having a second therapeutically effective intensity; automatically monitoring said irradiated tissue; and automatically terminating said irradiating when said monitoring indicates that said near-infrared laser light and said visible laser light have been applied to said tissue in amounts therapeutically effective to treat said disorder.
3. The method of claim 2 characterised in that said monitoring comprises noninvasively determining subsurface intensity of at least one of said near-infrared laser light and said visible laser light.
4. The method of claim 3 characterised in that said noninvasive determination comprises analyzing a radial dependence of a diffuse reflectance from said tissue of at least one of said near-infrared laser light and said visible laser light.
5. The method of claim 4 characterised in that said diffuse reflectance is detected from at least two detection points on a surface of said tissue, and wherein said two detection points are at separate positions along a radius originating at a surface focal point of said laser lights.
6. The method of any of claims 2-5 characterised by

automatically adjusting an intensity of at least one of said near-infrared laser light and said visible laser light in response to information obtained by said monitoring.

7. The method of any of claims 2-6 characterised in that said tissue comprises musculo-skeletal soft-tissue.

8. The method of any of claims 2-7 characterised in that said near-infrared laser light has a wavelength of 750 to 1000nm.

9. The method of any of claims 2-8 characterised in that said visible laser light has a wavelength of 450 to 749nm.

10. The method of any of claims 2-9 characterised in that said near-infrared laser light has a peak intensity of 0 to 2000 watts/cm².

11. The method of any of claims 2-10 characterised in that said visible laser light has a peak intensity of 0 to 2000 watts/cm².

12. The method of any of claims 2-11 characterised in that said near-infrared laser light and said visible laser light are pulsed.

13. The method of any of claims 2-12 characterised in that said near-infrared laser light is pulsed at a first frequency and said visible laser light is pulsed at a second frequency different from said first frequency, and wherein signals of said near-infrared laser light and said visible laser light are detected by a common sensor and filtered by frequency.

14. The method of any of claims 2-13 characterised in that said irradiating is terminated when said monitoring indicates that at least one of said near-infrared laser light and said visible laser light has penetrated to a sub-surface region of said tissue in an amount therapeutically effective to treat said disorder.

15. A method for administering a predetermined dose of radiation to a distal target tissue characterised by the steps of: irradiating a proximal tissue adjacent said distal target tissue with at least one laser light which penetrates through said proximal tissue to administer radiation to said distal target tissue; automatically monitoring said proximal tissue to determine whether to terminate said irradiating, said monitoring comprising detecting a radial dependence of a diffuse reflectance from a surface of said proximal tissue of said at least one laser light; and automatically terminating said irradiating when said monitoring indicates that said predetermined dose

of laser light has been applied to said distal target tissue.

16. The method of claim 15 characterised in that said diffuse reflectance is detected from at least two detection points on said surface of said proximal tissue, and wherein said two detection points are at separate positions along a radius originating at a surface focal point of said at least one laser light.

17. The method of claim 15 or claim 16 characterised by automatically adjusting an intensity of said at least one laser light.

18. The method of any of claims 15-17 characterised in that said predetermined dose is an amount therapeutically effective to treat a disorder.

19. A laser apparatus adapted to perform the method of claim 15 characterised by at least one laser; a power supply in electrical communication with said at least one laser; at least one detector adapted to detect radiation remitted from two points on said target surface along a radius originating at a focal point of said at least one laser on said proximal tissue; and control logic electronics adapted to automatically adjust an output of said at least one laser based on said remitted radiation detected by said at least one detector.

FIG. 1

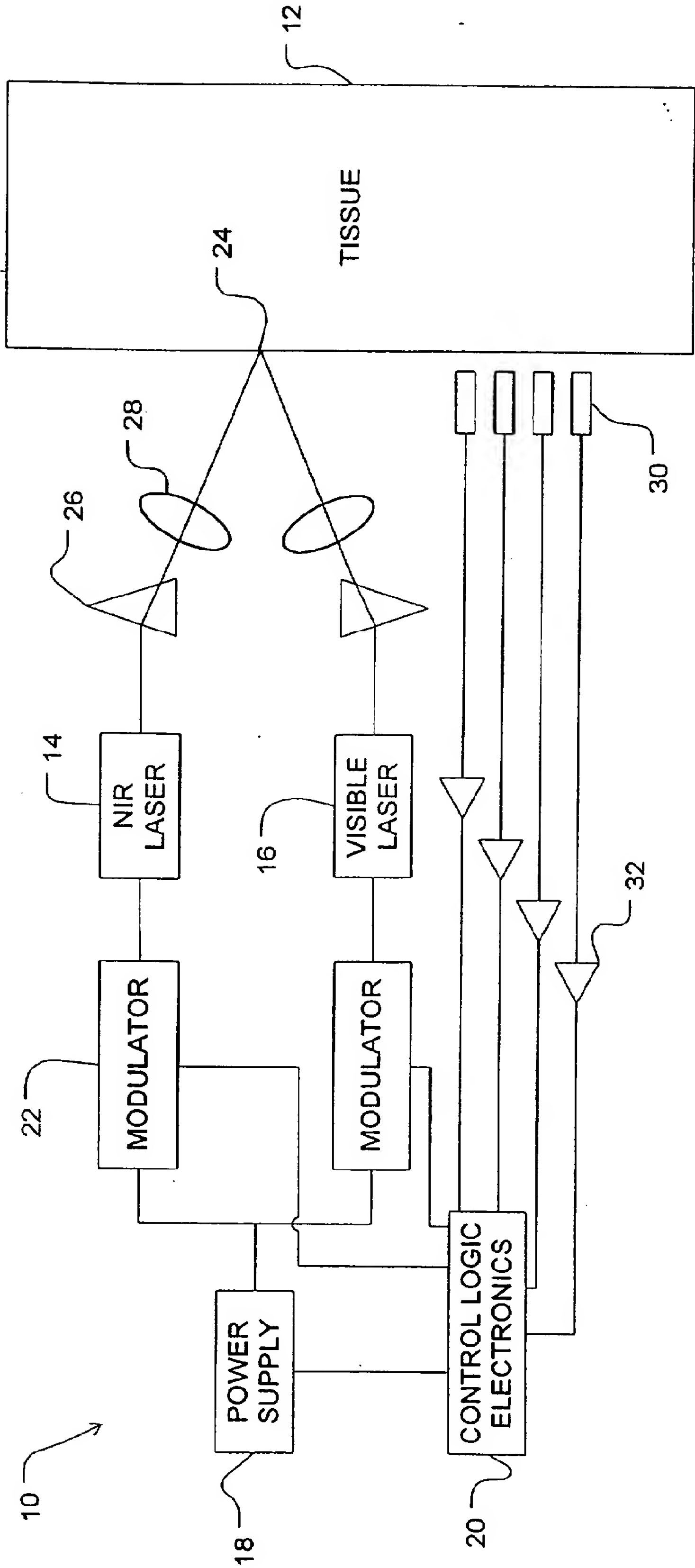


FIG. 2

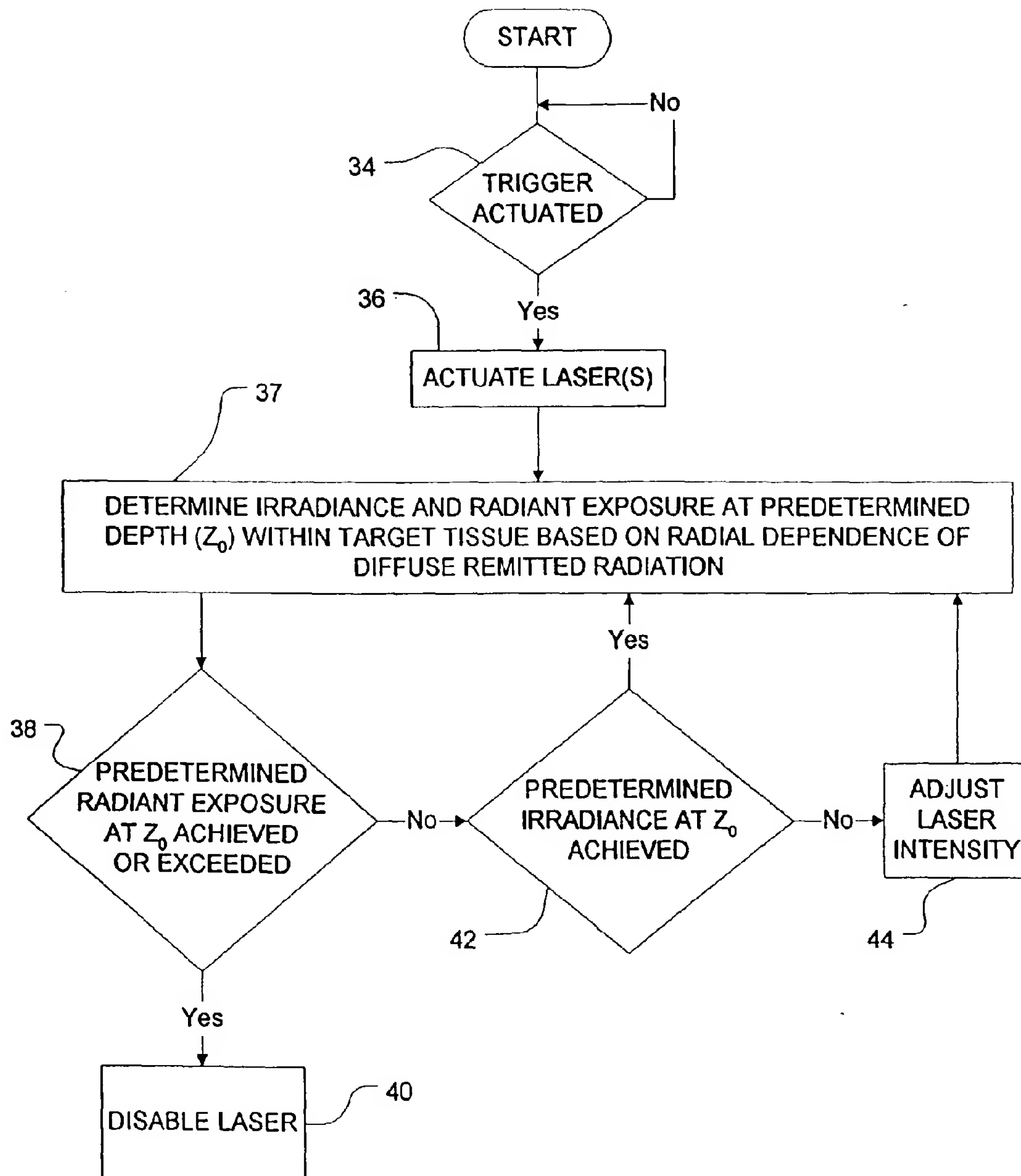


FIG. 3

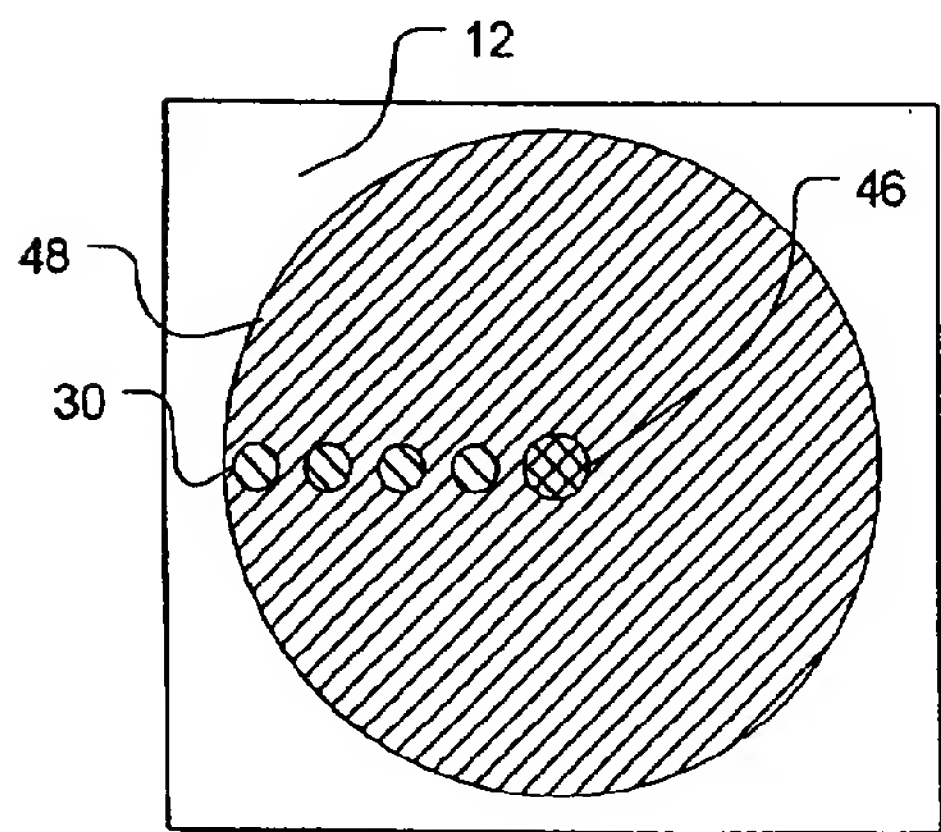
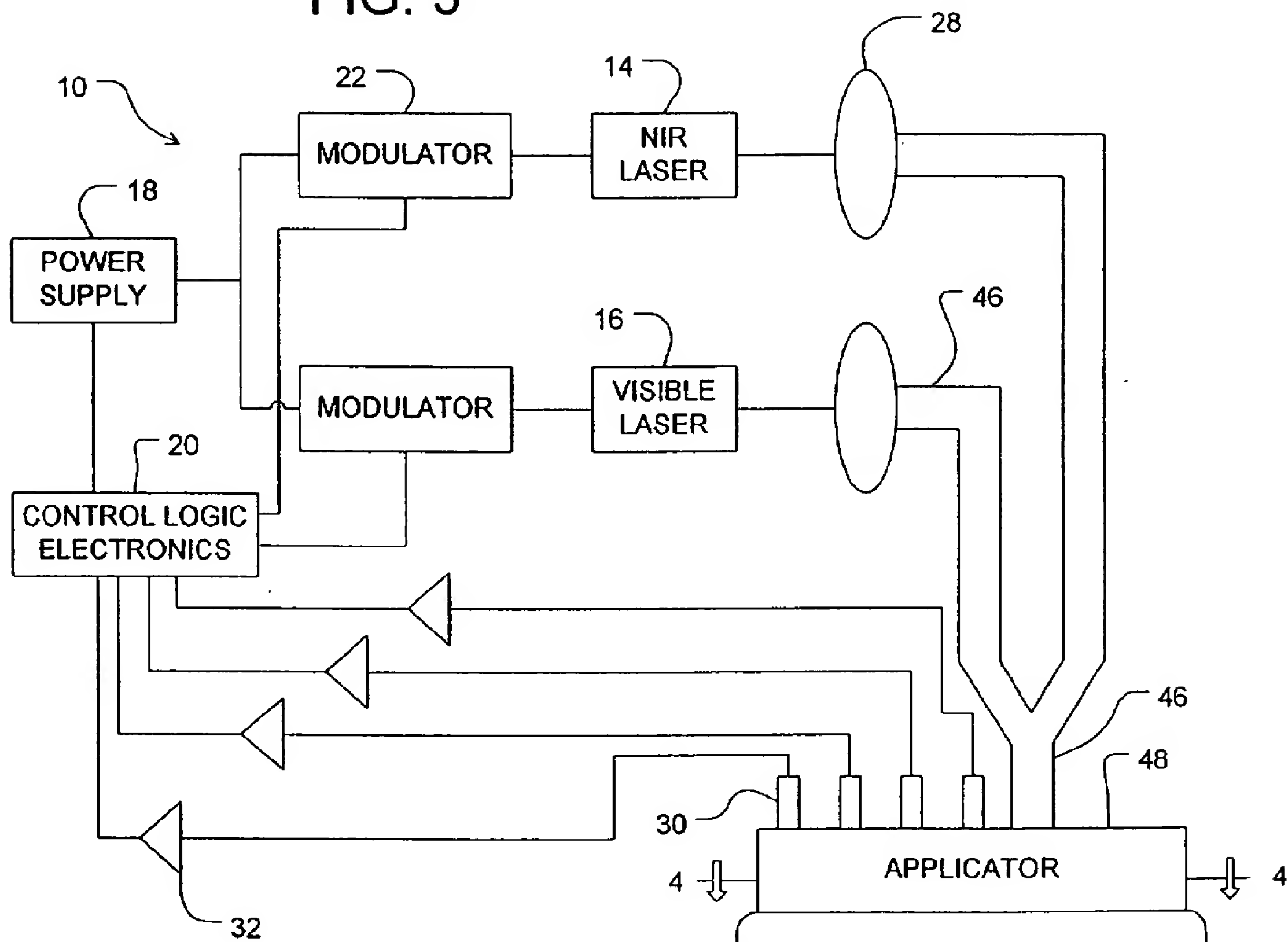


FIG. 4

(12)

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(54)

Hand apparatus for light delivery

(57) A hand apparatus comprises a housing, an optical connector (20) provided in the housing adapted for connection to a light source (3), and an elongate sleeve

(30). The sleeve (30) has a light emitter (32) at one end and an optical carrier (40) extending from the optical connector (20) to the light emitter (32).

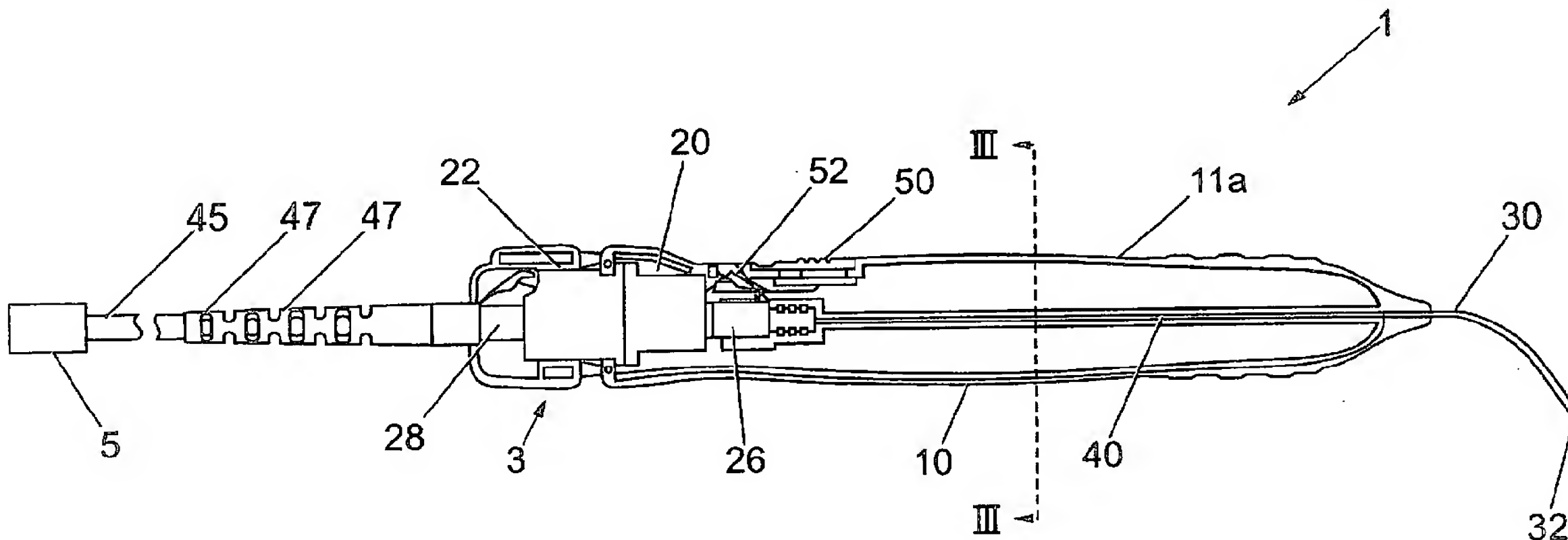


Fig. 1

Description

[0001] This invention relates to a hand apparatus for delivery of a beam of light, for example a collimated laser beam, to a point of application.

In particular the invention relates to a hand apparatus for delivery of a laser beam to a point of application on a tooth in a patient's mouth.

[0002] Hand pieces are used in medicine, dentistry and other forms of treatment to apply light locally to an area being treated. The light may be generated at a base unit and transmitted along a cable to a fixed hand piece. Alternatively the base unit may include a power source, with electrical power transmitted along a cable to a hand piece to generate the light at the hand piece itself. The flexible cable connection allows the operator of the hand piece to move the hand piece easily to the required point of application.

[0003] The known hand pieces suffer from the disadvantage that they must be sterilised between uses. The hand pieces contain precise optical components, so that they cannot be sterilised in the way that mechanical apparatus can. One solution is to provide a disposable sleeve around the hand piece. The sleeve is discarded and replaced between uses of the hand piece. However this solution suffers from the disadvantage that the sleeve cannot be totally effective in eliminating contamination from one use to the next.

[0004] It is an object of the present invention to provide a hand apparatus for delivery of a beam of light, for example a collimated laser beam, to a point of application, wherein the apparatus is inexpensive to manufacture and simple to connect to a light source, so that the hand apparatus can be used as a single use apparatus, eliminating the requirement to sterilise the apparatus for reuse.

[0005] According to a first aspect of the present invention there is provided a hand apparatus comprising a housing, an optical connector provided in the housing adapted for connection to a light source, an elongate sleeve having a light emitter at one end, and an optical carrier extending from the optical connector to the light emitter.

[0006] Preferably the optical connector is a male or female optical connector adapted for connection of optical telecommunication fibres. Preferably the optical connector includes a resiliently biased optical coupler to ensure contact between the optical coupler of the connector and the light source to which it is to be connected.

[0007] The apparatus may include a safety means which prevents light being transmitted if the optical connector is disconnected from the light source. Preferably the apparatus includes a switch adapted to operate a detent member which allows disconnection of the connector from the light source upon operation of the switch.

[0008] The light emitter may be an isotip emitter of the sort described in United States Patent No. 5,073,402.

[0009] Preferably the housing is of moulded plastic. The housing may be provided in two snap-fit parts. Preferably the housing is an elongate housing and includes means for retaining the optical carrier within the housing. Preferably the retaining means is adapted to permit longitudinal movement of the optical carrier relative to the channel during connection of the connector to a light source.

[0010] Preferably the retaining means includes an internal channel extending from the connector to the sleeve. Preferably the optical carrier extends along the channel.

[0011] Preferably the optical carrier includes at least one optical fibre.

[0012] The apparatus may also comprise a fluid delivery system. Preferably the fluid delivery system includes a reservoir, a fluid outlet adjacent the light emitter, and a conduit connecting the reservoir and the fluid outlet. The conduit may allow the passage of fluid from the fluid reservoir to the outlet adjacent the light emitter via the housing and the sleeve.

[0013] Preferably the sleeve is a resiliently flexible sleeve. The sleeve may be plastically deformable such that an operator can deform the sleeve to a required shape. Preferably the sleeve is adapted to permit longitudinal movement of the optical carrier relative to the sleeve upon deformation or flexing of the sleeve. Preferably the sleeve is of stainless steel.

[0014] According to a second aspect of the present invention there is provided a light delivery system comprising a light source and a hand apparatus, the light source including a first optical connector and the hand apparatus including a second optical connector, wherein the first and second optical connectors are male and female optical connectors adapted for connection of optical telecommunication fibres.

[0015] Preferably the first optical connector includes a first optical coupler and the second optical connector includes a second resiliently biased optical coupler to ensure contact between the first and second optical couplers when the first and second optical connectors are connected.

[0016] The light delivery system may include a safety means which prevents light being transmitted if the optical connector is disconnected from the light source. The safety means may be provided on the light source or the hand apparatus. Preferably the light delivery system includes a switch adapted to operate a detent member which allows disconnection of the first and second optical connectors upon operation of the switch.

[0017] Preferably the hand apparatus further comprises a housing, an elongate sleeve having a light emitter at one end, and an optical carrier extending from the second optical connector to the light emitter.

[0018] The light delivery system may also comprise a fluid delivery system. Preferably the fluid delivery system includes a reservoir, a fluid outlet adjacent the light emitter, and a conduit connecting the reservoir and the

fluid outlet. The conduit may allow the passage of fluid from the fluid reservoir to the outlet adjacent the light emitter via the housing and the sleeve.

[0019] An embodiment of the invention will now be described, by way of example only, with reference to the accompanying figures, where:

Fig. 1 is a cross sectional view of a hand apparatus according to a first embodiment of the invention;

Fig. 2 is an isometric cross sectional view of the hand apparatus of Fig. 1;

Fig. 3 is a partial cross sectional view at III-III of the hand apparatus of Fig. 1;

Fig. 4 is an isometric view of the hand apparatus of Fig. 1; and

Fig. 5 is a partial enlarged view of the switch of the hand apparatus of Fig. 1.

[0020] Referring to Figs. 1 and 2 there is shown a hand apparatus 1 according to an embodiment of the present invention, comprising a housing 10, a second optical connector 20 provided in the housing 10 and adapted for connection to a light source 3, an elongate sleeve 30 having a light emitter 32 at one end, and an optical carrier 40 extending from the optical connector 20 to the light emitter 32.

[0021] The second optical connector 20 is connected to a first optical connector 22 provided in a connector housing 24. Both connectors 20, 22 are typically standard optical telecommunication connectors such as those manufactured by Stratos Lightwave. Standard connectors allow accurate optical coupling of the fibre ends within a low tolerance (typically 1 micron).

[0022] The first optical connector 22 is typically a female connector and the second optical connector 20 is typically a male connector. This ensures that no optical carriers 40 are exposed while the first optical connector 22 is connected to the light source 3 but not connected to the second optical connector 20.

[0023] The optical carrier 40 comprises a number of optical fibres arranged in a bundle and generally surrounded by a sheath (not shown). The light source 3 includes a light generator 5 and an optical cable 45 comprising a number of optical fibres within a shielding connecting the light generator 5 to the first optical connector 22 in the connector housing 24. The cable 45 may include ribs or thickened portions 47 adjacent to the hand apparatus for increased flexural strength, flexural stiffness and fatigue life.

[0024] A switch 50 is provided on the housing 10. The switch may be seen most clearly in Fig. 5. The switch 50 is connected through a slot 58 to a cam member 54. When the switch 50 is operated in the direction of arrow 60, the cam member 54 is driven forward in the direction

of arrow 60. This forward travel of the cam member 54 causes the hinged latch control member 56 to move downwardly and engage with a latch member 52 which also moves downwardly and causes the first optical connector 22 to decouple from the second optical connector 20. An abutment member 62 is also connected to the switch 50 and after a predetermined amount of forward movement, during which the optical connector 22 is decoupled as described above, abuts the first optical connector 22 causing the first and second optical connectors to separate. This separation provides a visible signal to the operator that the hand piece 1 can be removed from the light source 3. It is to be understood that the switch mechanism illustrated in Fig. 5 is only one possible switch mechanism and may be replaced by any suitable hand operated coupling and decoupling system.

[0025] A suitable safety means (not shown) may also be provided such that light may only be transmitted from the first optical coupler 22 if the first optical coupler 22 is connected to the second optical coupler 20. The safety means may be an electronic switch which is broken when the hand apparatus 1 is disconnected from the light source 3, causing an electronic signal to be sent along wires (not shown) in the cable 45 to turn off the light generator 5.

[0026] The housing 10 comprises two components 11a, 11b joined to each other using snap-fit connection or other suitable means. The housing 10 is typically manufactured from moulded plastic. The housing is substantially cylindrical in shape.

[0027] Fig. 3 shows one component 11a of the housing in cross section (at III-III in Fig. 1) and also the optical carrier 40. The housing, at this axial location, includes a web portion 14 extending from the outer circumference towards the centre. The web portion 14 divides into two split web portions 15, which together with the two split web portions 15 of the other component 11a define a channel 16 in which the optical carrier 40 is supported in a way which allows transverse movement within the channel.

[0028] The ends 18 of the outer circumferential portion of the component 11a are profiled to allow snap-fit connection with correspondingly shaped ends 18 of the other component 11b. When the two components 11a, 11b of the housing 10 are joined, the split web portions 15 of the two components of the housing 10 form a channel which houses the optical carrier 40 and extends along the axis of the housing 10 from the second optical connector 20 to the sleeve 30.

[0029] Fig. 4 shows the hand apparatus with the two components 11a, 11b of the housing 10 joined. At one region of the exterior surface of the housing 10 there is provided a grip portion 12 having an embossed surface. This region is typically located near the sleeve end of the housing.

[0030] Referring also to Figs. 1 and 2, the sleeve 30 is fixed at one end within the housing 10. At the other

end of the sleeve 30 is located the light emitter 32. The light emitter may be an isotip optical emitter of the sort described in United States Patent No. 5,073,402.

[0031] The internal diameter of the sleeve 30 is substantially greater than the external diameter of the optical carrier 40. The sleeve 30 is typically made of stainless steel or other suitable metal. This allows the sleeve 30 to be permanently bent into a position desirable to the user. Because the optical carrier 40 is free to move longitudinally relative to the sleeve 30, bending the sleeve 30 causes no damage to the optical carrier 40.

[0032] The optical carrier 40 is constrained where it is joined to the second optical connector 20 and is fixed at the light emitter 32 but is otherwise unconstrained, and is free to move laterally within the channel 16 and within the sleeve 30. The optical carrier 40 is rigidly secured to the second coupler 26, which is mounted within the second connector 20 in a resiliently biased manner, in order to ensure a firm connection between the second coupler 26 and the first coupler 28, which is fixedly mounted in the first connector 22. When the first 22 and second 20 optical connectors are connected, the second coupler 26 moves longitudinally relative to the second connector 20 as it is brought into contact and pressed against the first coupler 28. It is therefore important that the housing accommodates relative longitudinal movement of the optical carrier 40, which is fixed to the second coupler 26, and the housing 10, which is fixed to the second connector 20. This relative longitudinal movement is accommodated by the fact that the channel 16 in which the optical carrier 40 sits is much wider than the carrier itself. Hence the carrier 40 is free to adopt a serpentine profile in order to accommodate the longitudinal movement of the end attached to the second coupler 16. The dimensions of the channel 16 typically allow up to 2 mm relative longitudinal movement.

[0033] The hand apparatus 1 as described is inexpensive to produce. It is intended that the hand apparatus 1 be a disposable unit. The light source 3, including the first optical connector 22 and the connector housing 24 and the associated cabling 45 are intended to be more permanent. The hand apparatus 1 can readily be disconnected from the light source 3 by simple separation of the first and second optical connectors 20, 22 and replaced by another hand apparatus. If required different types of hand apparatus 1 having different lengths of housing 10 and/or different lengths and/or shapes of sleeve 30 may also be provided.

[0034] The hand apparatus 1 may also be used to provide other functions, particularly dental functions. For instance, a fluid conduit (not shown) may also be provided within the housing 10 that supplies fluid, such as mouthrinse, to a spout (not shown) located adjacent to the light emitter 32.

[0035] Modifications and variations to the invention described above are possible without departing from the scope of the invention.

Claims

1. A hand apparatus comprising:
 - a housing;
 - an optical connector provided in the housing adapted for connection to a light source;
 - an elongate sleeve having a light emitter at one end, and an optical carrier extending from the optical connector to the light emitter.
2. A hand apparatus according to Claim 1, wherein the optical connector is a male or female optical connector adapted for connection to optical telecommunication fibres.
3. A hand apparatus according to Claim 1 or Claim 2, wherein the optical connector includes a resiliently biased optical coupler to ensure contact between the optical coupler of the connector and the light source to which it is to be connected.
4. A hand apparatus according to any preceding claim, including safety means adapted to prevent light being transmitted if the optical connector is disconnected from the light source.
5. A hand apparatus according to any preceding claim, wherein the apparatus includes a switch adapted to operate a detent member which allows disconnection of the connector from the light source upon operation of the switch.
6. A hand apparatus according to any previous claim, including retaining means for retaining the optical carrier within the housing, the retaining means being adapted to permit longitudinal movement of the optical carrier relative to the channel during connection of the connector to a light source.
7. A hand apparatus according to Claim 6, wherein the retaining means comprises an internal channel extending from the connector to the sleeve, the optical carrier extending along the channel.
8. A hand apparatus according to any preceding claim, including a fluid delivery system comprising:
 - a reservoir;
 - a fluid outlet adjacent the light emitter; and
 - a conduit connecting the reservoir and the fluid outlet, the conduit allowing the passage of fluid from the fluid reservoir to the outlet adjacent the light emitter via the housing.
9. A hand apparatus according to any preceding claim, wherein the sleeve is adapted to permit longitudinal movement of the optical carrier relative to

the sleeve upon deformation or flexing of the sleeve.

10. A hand apparatus according to any preceding claim, wherein the sleeve is a resiliently flexible sleeve. 5

11. A hand apparatus according to any of Claims 1 to 9, wherein the sleeve is plastically deformable. 10

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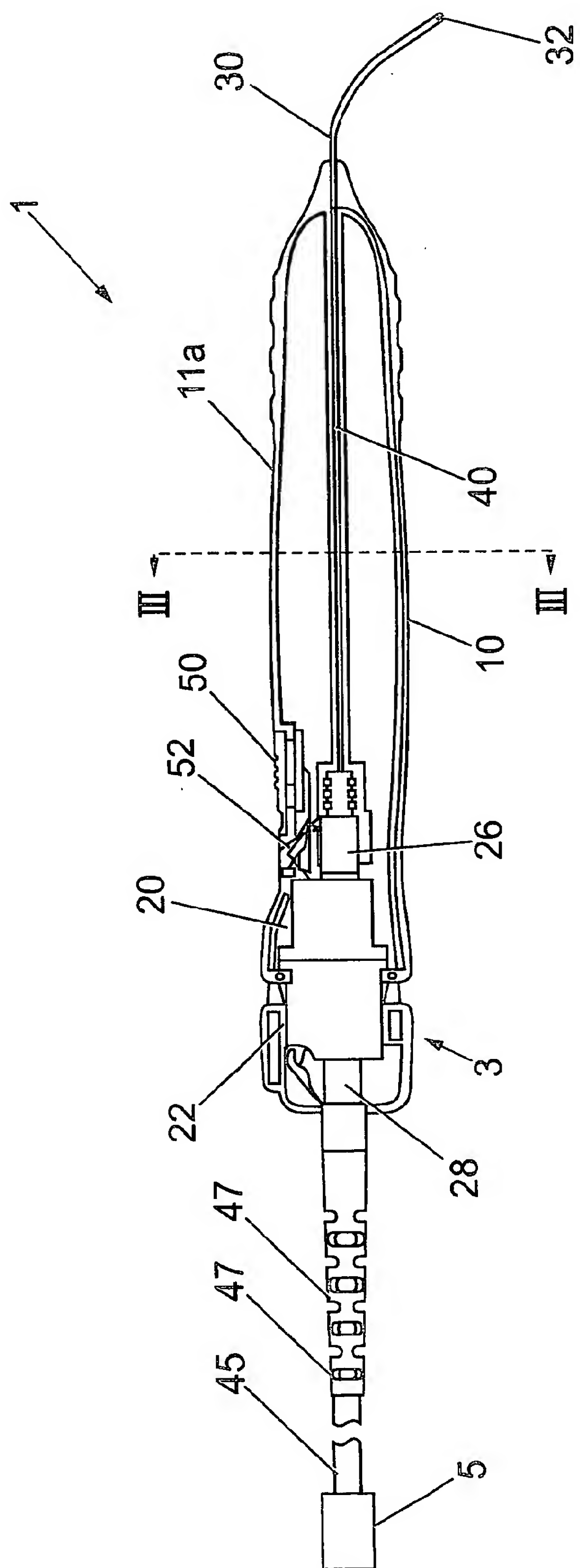


Fig. 1

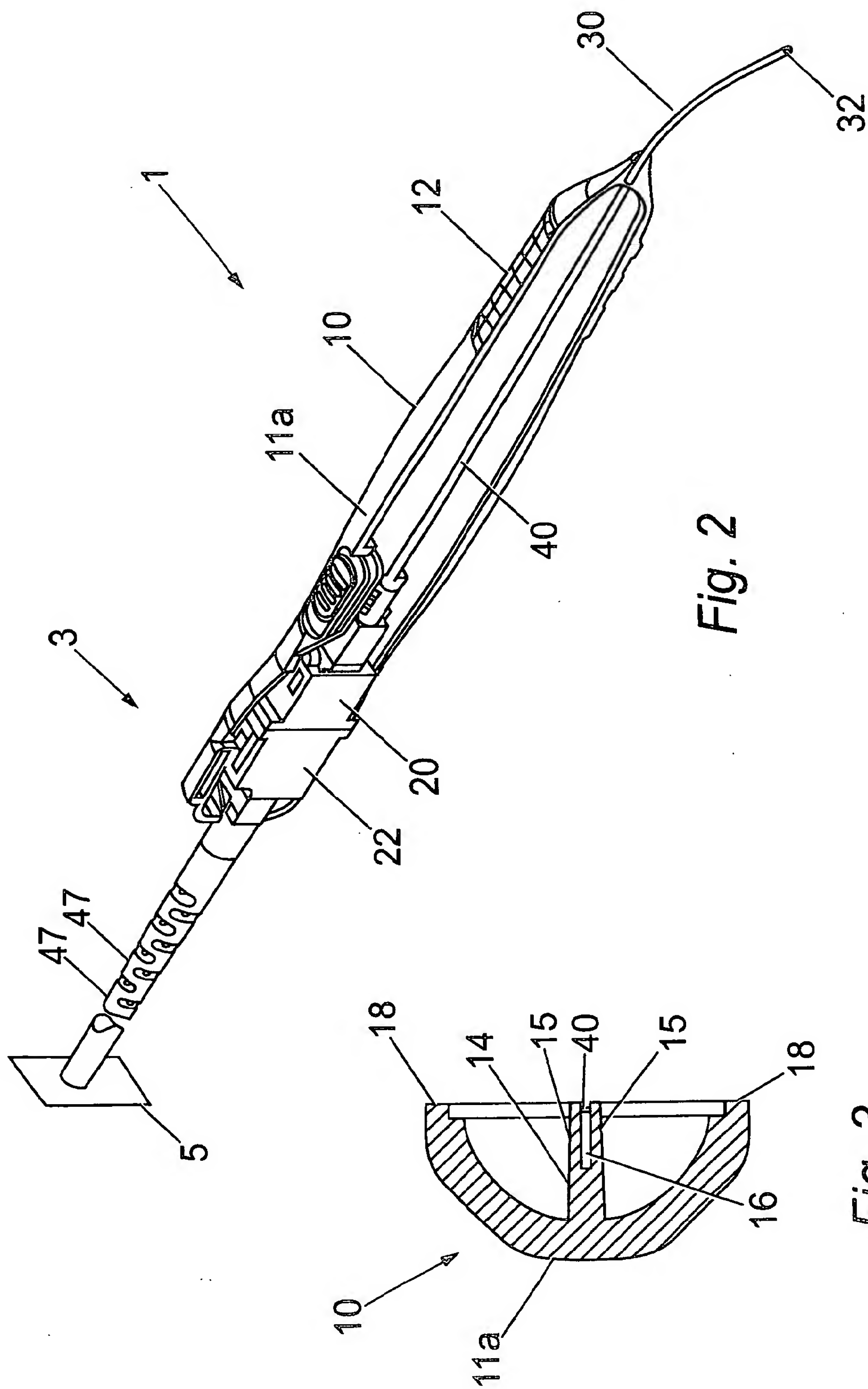
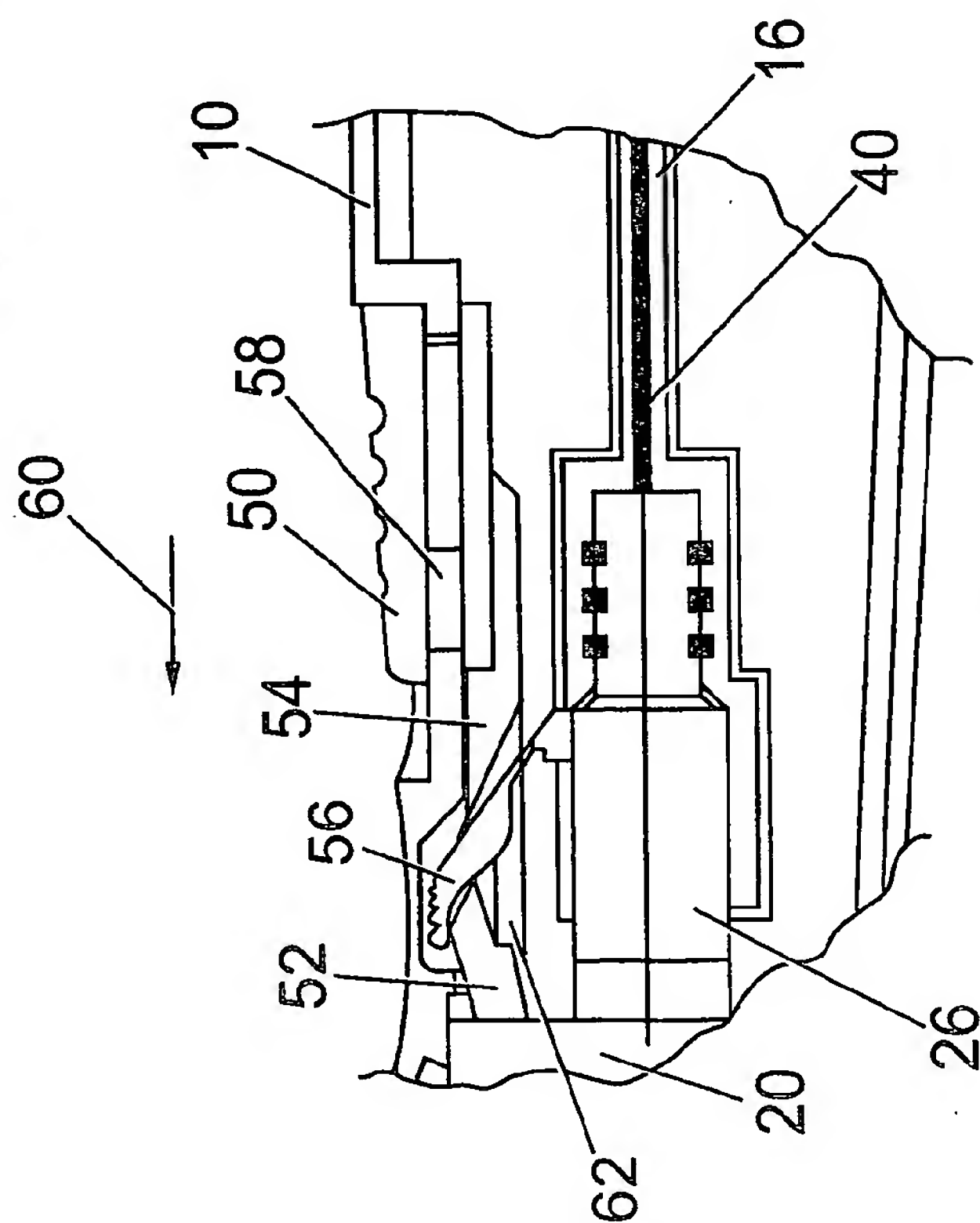
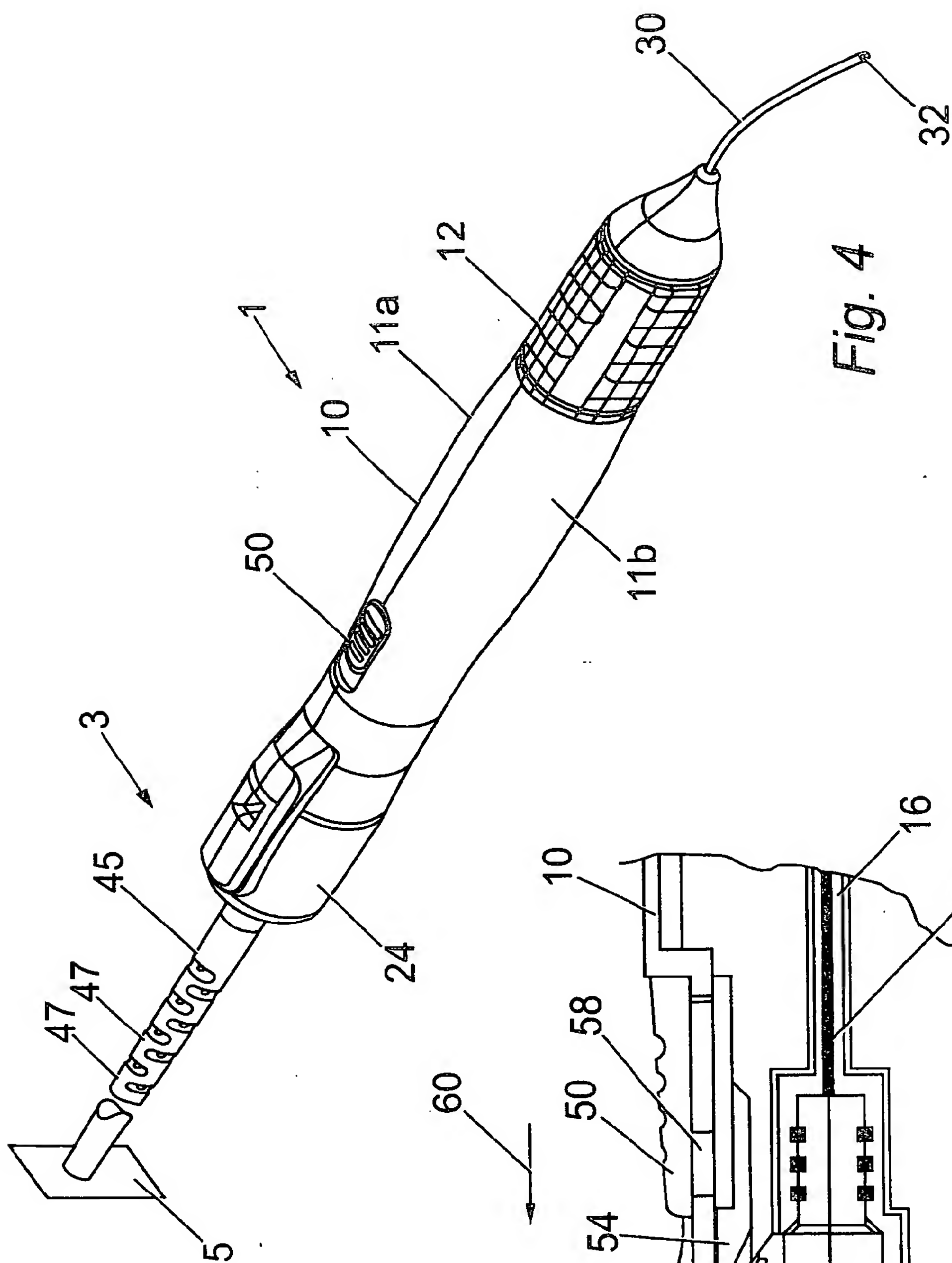
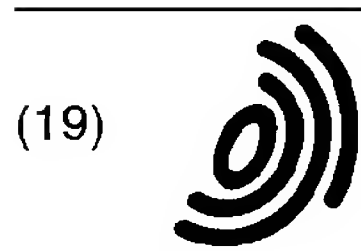


Fig. 2

Fig. 3





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(54) **Hair removal apparatus using optical pulses**

(57) Apparatus for simultaneously effecting the re-
moval of multiple hairs from a skin region 20 by using
light energy to destroy hair follicles 40 in the region is
disclosed. Light energy is applied to the region through
an applicator 18 which converges the light energy to en-
hance destruction of desired portions of the follicles, is
preferably pressed against the skin region to deform the
upper layers of the skin reducing the distance from the
skin surface to portions of hair follicles which are to be
destroyed, including the bulge and papilla of the follicles,
and which applicator is preferably cooled 50, 52 to min-
imize or eliminate thermal damage to the epidermis in
the region being irradiated. Parameters for the irradiation,
including pulse duration, are selected to effect complete
damage of desired portions of the hair follicles in
the region with minimal damage to surrounding tissue
and to the patient's epidermis.

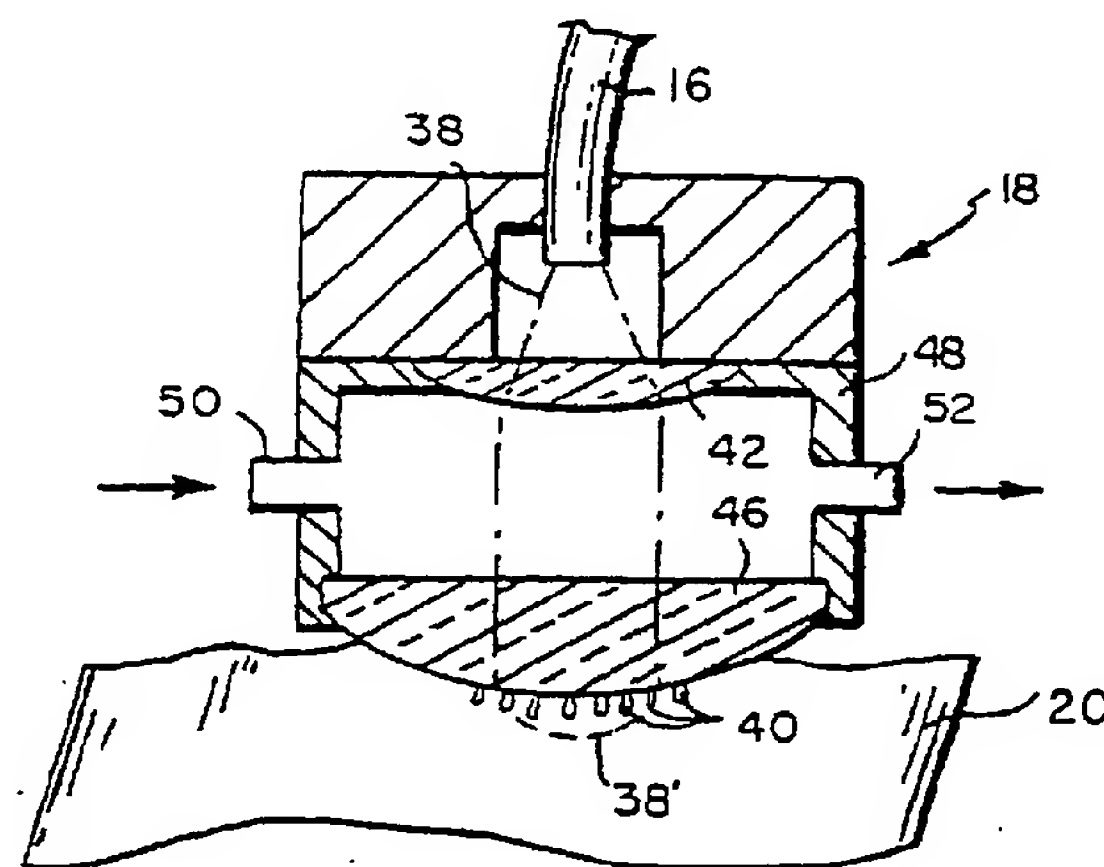


FIG. 2A

EP 1 495 735 A1

Description**Background**

5 **[0001]** This invention relates to apparatus for hair-removal using optical radiation.

[0002] Excess hair (hypertrichosis) and/or unwanted hair are common dermatological and cosmetic problems, and can be caused by heredity, malignancy, or endocrinologic diseases, for example hirsutism (i.e., excess hair due to hormones such as androgens). Hair can be temporarily removed using a number of techniques including wax epilation, depilatory creams, and, of course, shaving. Alternatively, hair can be more permanently removed using electrolysis;
10 this process involves insertion of a current-carrying needle into each hair follicle, and is often painful, inefficient, and time consuming.

[0003] Optical-based methods, such as the use of laser light, have also been used for hair removal. US-A-4 388 924, for example, describes irradiation of individual hair follicles using a laser; in this method, heating of the hair's root section causes coagulation in local blood vessels, resulting in destruction of the follicle and thus in removal of the hair.

15 Related techniques, such as those described in

[0004] US-A-5 226 907, involve destruction of the follicle by first applying a light-absorbing substance to the region of interest, the light-absorbing substance migrating at least part-way into the follicle, removing the excess light-absorbing substance, and then irradiating the region to heat the substance and thus the follicle to cause destruction of the follicle.

20 **[0005]** The above prior art techniques suffer from a number of limitations. First, techniques for irradiating an individual hair follicle are time consuming and therefore are generally not practical for removing hairs other than from a very small region or from a region having few hairs situated therein. The procedure can also be painful, particularly if a needle-like element is inserted into the hair follicle to facilitate light energy reaching the bulge and the root or papilla, parts of the hair follicle which must be destroyed in order to prevent regrowth of the hair. Where the irradiation source is not
25 inserted into the follicle, it is difficult to get sufficient energy to the required portions of the follicle to result in destruction thereof without also causing significant damage to the surrounding tissue and thus causing pain and injury to the patient.

[0006] While the technique of the latter patent is advantageous in that it permits a number of hairs in a given region to be simultaneously removed, it is difficult with this technique to get the light-absorbing substance or chromophore deep enough into the follicle to effect destruction of the papilla. Further, this technique results in substantial energy
30 being applied to and absorbed by the epidermis and other skin layers in the region being treated, with significantly reduced energy reaching the root or papilla of the follicle. Total destruction of the follicle, and therefore permanent, or at least long term, hair removal is therefore difficult to achieve, particularly without risking damage to the epidermis and other layers of skin within the region.

35 **[0007]** A need therefore exists for improved apparatus for performing hair removal which facilitates optical energy reaching the bulge and base, or root of hair follicles in a region while minimizing damage to the epidermis in the region, thereby minimizing patient discomfort and potential adverse side effects from the treatment.

Summary of the invention

40 **[0008]** The present invention provides in a first aspect apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising: an applicator;

a source of optical radiation; and

45 an optical path from the source of optical radiation to the said surface of the said applicator, which path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed through the said surface of the said applicator to the said skin region, characterised in that the said radiation has a wavelength between 680nm and 1200nm, preferably between 680nm and 900nm, and a fluence of between 10J/cm² and 200J/cm², and in that the duration of the radiation on the said skin region is 50µs to 200ms, preferably 5ms to 200ms.

50 **[0009]** In a second aspect the invention provides apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising an applicator, which preferably comprises a surface adapted to be in contact with the skin surface in a skin region from which hair is to be removed; a source of optical radiation; and

55 an optical path from the source of optical radiation to the said surface of the said applicator, which path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed through the said surface of the said applicator to the said skin region,

characterised in that the apparatus further comprises means for cooling the said surface of the applicator to a temperature below that of the said skin region.

[0010] In a third aspect, the invention provides apparatus for the simultaneous removal of a plurality of hairs from a

skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising an applicator comprising a surface adapted to be in contact with the skin surface in a skin region from which hair is to be removed; a source of optical radiation; and an optical path from the source of optical radiation to the said surface of the said applicator, which path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed through the said surface of the said applicator to the said skin region, characterised in that at least the said surface of the applicator is formed of a material having a refractive index which substantially matches the refractive index of the skin surface in the said skin region.

[0011] In a fourth aspect, the invention provides apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising: an applicator comprising a surface adapted to be in contact with the skin surface in a skin region from which hair is to be removed; a source of optical radiation; and an optical path from the source of optical radiation to the said surface of the said applicator, which path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed through the said surface of the said applicator to the said skin region, characterised in that further comprising an element in the optical path for converging the optical radiation as it leaves the applicator through the said surface.

[0012] In a fifth aspect, the invention provides an applicator suitable for use in practising a method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin, from a skin surface, comprising: a housing; a transmitter of optical radiation into said housing; a surface disposed on the housing having a convex shape and adapted to be in pressure contact with the skin surface in the said skin region; an optical path through said housing from the transmitter of optical radiation to the said surface which path is substantially transparent to optical radiation at the said selected wavelength; an element in the optical path for converging the optical radiation as it leaves the applicator through the said surface; and means for cooling the said surface to a temperature below that of the said skin region.

[0013] The technique of using the apparatus of the invention involves placing the applicator in contact with the skin surface in the skin region and applying optical radiation of a selected wavelength and of a selected flux through the applicator to the skin region for a predetermined time interval. The applicator is preferably pressed against the skin surface, thereby reducing the distance from the applicator to the papilla of the hair follicles and facilitating destruction thereof. Further, the skin surface in the skin region can be cooled to a selected depth during the applying of optical radiation to the skin region and/or prior thereto. This allows the papilla of the hair follicles to be significantly heated without damage to the skin surface in the skin region up to the selected depth.

[0014] In some embodiments, the applicator is utilized to cool the skin surface in the skin region to the selected depth and the selected depth is preferably at least equal to the depth of the epidermis layer of the skin (i.e., the layer of the skin closest to the skin surface). The cooling by the applicator may for example be accomplished by cooling at least the surface of the applicator in contact with the skin surface, such cooling preferably being accomplished both before and during the irradiation of the skin. Preferably, the cooling of the applicator is accomplished by passing a cooling fluid such as water through the applicator, preferably through a channel near the surface. It is preferred that irradiation of the skin surface not be performed until the skin region has been cooled to substantially the selected depth. Most preferably, cooling is performed both before and during irradiation, and the selected flux and predetermined exposure time (i.e., time interval for irradiation) are selected such that there is at most minimal heating of skin in the skin region to the selected depth, while there is sufficient heating of hairs and follicles below the selected depth to at least damage the hairs and follicles without causing significant damage to tissue surrounding the follicles. A preferred time interval for irradiation is 2ms to 100ms.

[0015] In some embodiments, the applicator converges optical radiation applied to the skin region, thereby further facilitating irradiation of the follicle papillas. Preferably the element in the applicator which converges the radiation is a lens. In preferred embodiments, the applicator also has a convex surface in contact with the skin surface, applying substantially uniform pressure thereto to deform the underlying skin surface. In other embodiments, the applicator is designed to form a fold of the skin in the skin region and to apply optical radiation to two substantially opposite sides of the fold. For example, the applicator may have a slot formed in the surface thereof in contact with the skin surface, with at least a portion of the skin region being drawn up into the slot and optical radiation being applied to the skin region from at least two opposite sides of the slot.

[0016] In some embodiments a substantial refractive index match be maintained between the applicator and the skin surface in said skin region. Such refractive index match may be provided by a layer of refractive index matching substance between the applicator and the skin surface in a skin region and/or by forming the applicator of a material which at least for the surface in contact with the skin region has a refractive index which substantially matches that of the skin surface.

[0017] To facilitate hair removal, hairs in the skin region may be shaved prior to irradiation. However, it may be preferable to epilate the hairs in the skin region before irradiation. When hairs are epilated, destruction of the follicles can be facilitated by filling the follicles from which the hairs have been epilated with a substance which preferentially

absorbs optical radiation at the selected wavelength being used for irradiation (i.e., a chromophore). Further, where only temporary hair removal is desired, this may be accomplished for a period of up to several weeks, relatively painlessly, by applying the chromophore to the area, which has been preferably pre-shaved, which chromophore migrates into the hair follicles to a depth of a few millimeters, roughly to the depth of the sebaceous gland. Low level irradiation applied through the applicator to the skin region will then result in the destruction of the hair without destroying the follicle.

[0018] In one embodiment, the surface of the applicator in contact with the skin has a convex shape while in another embodiment the surface has a slot formed therein, with the optical path leading to at least two opposite sides of the slot, and the applicator includes a means for drawing at least a portion of the skin region into the slot, this means for drawing preferably includes a vacuum applying element.

Brief description of the drawings

[0019] The invention will be further described, by way of example with reference to the drawings, in which:

Fig. 1 is a perspective view of a laser-based hair-removal device according to the invention;

Figs. 2A and 2B are cross-sectional views of an irradiating unit or applicator suitable for use with a hair-removal device of the invention, the applicator receiving, respectively, light from a fiber optic or fiber optic bundle, and from a mirror assembly;

Figs. 3A, 3B, and 3C are, respectively, an expanded, cross-sectional view of the contact device of the irradiating unit in direct contact with a hair-containing skin region, a cross-sectional, cut-out view showing the back-scattered optical fields at the contact device/epidermis interfacial region, and a cross-sectional cut-out view showing thermal transport at the interfacial region;

Fig. 4 is a plot showing the optical absorption spectra of melanin, hemoglobin, oxygenated hemoglobin, and water;

Figs. 5A and 5B show, respectively, the time and spatial profiles and the preferred optical field used during the hair-removal process;

Fig. 6 is a plot of the computer-generated optical intensity as a function of skin depth for different optical fields;

Fig. 7 is a photograph showing skin regions of a patient three months after being treated according to the hair removal method of the invention;

Figs. 8A, 8B and 8C are oscilloscope traces showing, following irradiation, the time-dependent temperature responses of, respectively, dry black hair, wet black hair, and live skin surrounding the black hair sample;

Fig. 9 is a plot showing the temperature rise as a function of laser pulse energy for dry hair (DH), wet hair (WH), and skin (S) samples of eight different patients;

Fig. 10A is a partial cross-sectional view of an applicator of the invention being used to practice an alternative embodiment of the invention wherein epilation and filling of empty follicles with a chromophore are performed before irradiation; and

Fig. 10B is a cross-sectional view of an applicator according to another embodiment being used for hair removal.

Detailed Description

[0020] Referring to Fig. 1, an exemplary laser-based hair-removal system 10 includes a light source 12, which may, for example, include one or more lasers for generating the irradiating field. The light source 12 may be optically coupled to a series of beam-manipulating optics 14 which, in turn, may be coupled via a fiber optic cable 16 (or other fiber optic device) to the irradiating unit or applicator 18. During the hair-removal therapy, the light source is powered by a voltage and current supply 19, and delivers a beam of light through the optics 14 and fiber optics 16 to the irradiating unit or applicator 18. The field is then delivered to a region 20 of a patient 22 (positioned, for example, on a table 25, a chair, or other suitable positioning element depending on the location of the region 20 on the patient's body) resulting in hair removal from the region 20. Once the desired region is treated, the irradiating unit can be easily moved along the patient 22, as indicated by arrows 27, and used to treat subsequent regions.

[0021] The spatial and temporal properties of the optical field determine the efficacy of the hair-removal process, and some of these properties may, if desired, be adjusted using a series of controls 24, 26, 28 located on various components of the hair-removal system 10. For example, using controls 24 located on the power supply, the optical intensity and pulse repetition rate of the irradiating field can be controlled by adjusting parameters such as the voltage, current, and switching rate for the laser's power supply. Other properties of the field, such as the wavelength and pulse duration, may be varied by controls 26 which adjust components (e.g., gratings, mirror or filter positions, shutters, or pulse-forming means) of the light source 12; however, for preferred embodiments wavelength would not be adjusted. Similarly, controls 28 can be used to adjust the modulating optics 14, resulting in control of properties such as mode quality, beam diameter, and coupling of the irradiating field into the fiber optics 16. All controls may be adjusted by

hand; and the system may also be operated (i.e., the laser turned on) by hand or, alternatively, by using a foot pedal 30 connected to the system 10.

[0022] In alternate embodiments, the light source, coupling optics, and irradiation unit may be encompassed in a single, hand-held device. In this case, the light source is preferably an array of diode lasers coupled directly to the irradiating unit, and is powered by a small external power supply. The compact nature of this type of optical system allows for a more controllable, manoeuvrable device, and additionally obviates the need for fiber optic delivery systems.

[0023] In order to effectively destroy the irradiated hair follicles without causing damage to the surrounding skin, the light field supplied by the system 10 and the irradiating unit 18 is designed to maximize the amount of light-induced heat deposited in the hair follicles, while reducing the degree of injury to the surrounding skin. It is preferred, for example, to deliver sufficient optical energy to several "target" regions on the hair follicle; radiation delivered to these regions results in complete and localized destruction of the follicles.

[0024] Prior to treatment, the region to be treated may be shaved in order to facilitate irradiation of the follicles. Alternatively, as will be discussed later, hairs in the region may be epilated and a chromophore may be applied to region 20, which chromophore migrates into the empty follicles. Excess chromophore may then be removed from the skin surface prior to irradiation. Prior to treatment, an anaesthetic may also be injected locally or applied to the skin surface and following treatment, patients may be treated with topical antibiotic ointments.

Mechanical structure

[0025] With reference now to Figs. 2A and 2B, the applicator or irradiating unit 18 of the hair-removal system allows delivery of the irradiating field 38 to hair follicles 40 located in the region 20. As shown in Fig. 2A, the field 38 may be delivered to the irradiating unit 18 using a fiber optic cable 16 (or other fiber optic device) containing one or more fibers or fiber optic bundles. In this case, after exiting the waveguide, the field 38 is typically spatially dispersed, and is preferably collected and roughly collimated using a plano-convex lens 42. Alternatively, as shown in Fig. 2B, the field may be delivered to the irradiating unit using, for example, one or more reflecting mirrors 44. This allows the field 38 to be roughly collimated prior to impinging on the lens 42. Depending on the focal length of the lens 42 and the mode quality of the irradiating field, the field is preferably condensed using, e.g., a plano-convex lens as shown in the figure. After passing through this optic, the beam then impinges on a lens or contact device 46 which is placed in contact with the skin region 20. The optical and mechanical properties of the contact device 46 are chosen to allow efficient coupling of the optical radiation into the skin region (resulting in a delivered field 38) and the thermal properties of the contact device are chosen to allow efficient coupling of heat from the skin region. Once delivered, the field is used to irradiate, heat, and then destroy the hair follicles 40. The contact device 46, in addition, is used to couple light and heat out of the superficial skin layer (i.e., epidermis) of the irradiated region. This allows the light-absorbing pigment (i.e., melanin) contained within the deep part of the hair follicles to be irradiated and selectively heated, permitting permanent destruction of the follicle, while potentially deleterious optical and thermal energy are simultaneously conducted out of the overlying skin layers. Thus, multiple hair follicles can be destroyed, permanently removing hair from the skin region without causing substantial pain or injury to the patient. The destroyed follicles are ultimately removed by the body.

[0026] Both the lens 42 and contact device 46 are preferably disposed in a housing 48 containing both entrance 50 and exit 52 ports for fluids such as cooling water and pure gas (i.e., nitrogen to prevent condensation on the lens) to flow into and out of; fluids may be used, for example, to cool the contact device 46, which, in turn, cools the skin surface. Alternatively, the housing 48 may include an electrically controlled cooler in order to provide accurate control over the temperature of the contact device 46. Preferably, when cooling means are used, the temperature of the surface layer or epidermis of the skin is reduced to between 4-15°C. In addition, in this case, it is preferred that a short time period (e.g., about 1 second) be allowed to elapse before irradiation in order to ensure that the epidermis is adequately cooled. An external casing 39, as indicated in Fig. 2B by the dashed line, or a fiber-coupling housing 37, as shown in Fig. 2A, may be used to connect the light-delivering means to the housing 48.

[0027] With reference now to Fig. 3A, the contact device 46 is preferably formed into a lens shaped in order to converge the irradiating field, preferably near the base of the hair follicles 40. In order to converge light, the contact device must be optically transparent at the irradiating wavelength, and preferably has a biconvex or plano-convex lens shape, preferably with an f number less than or equal to f/1.0, and a focal length of between about 0.5cm and 2cm. Control over the surface shape of the contact device allows the converged light field 38' to simultaneously irradiate various target portions of the hair follicle, resulting in efficient destruction. Typically, each irradiated hair shaft has a diameter of about 75 µm, with the entire follicle having a diameter of about 200 µm. After passing through the contact device 46, the light field 38' is preferably converged through the epidermis 56 of the skin layer (having a thickness, e.g., of about 0.1mm) and is condensed in the dermis 58 near the papillae 54 of the follicles 40. Because dermal thickness varies greatly over the body, the papillae may be superficial (as in, e.g., the eyelids and scrotum), but for most areas of interest (e.g., the face, axillae, and legs) the papillae are located at depths of approximately 4mm to 7mm beneath the epidermal surface. Located a few tenths of a millimeter below the papillae are neurovascular bundles 60 which

serve the metabolic and other needs of a hair matrix, the region of rapidly growing keratinizing cells, located in the papilla, which produce the hair shaft 55. The matrix, papilla, and the corresponding vascular bundle, as well as the bulge near the center of the follicle, represent the follicular targets to be irradiated/destroyed. Preferably, during irradiation of these regions, the field is pulsed, the pulse duration of the irradiation being kept short enough so that damage is localized to a small region of dermis (typically within about 0.2mm) surrounding each follicle in accordance with the principles of selective photothermolysis. The extent of damage is preferably much less than half the distance between neighboring follicles (typically between 1mm and 4mm); if it is significantly greater than this, the light-induced injury may result in a third-degree burn.

[0028] In addition to providing a light converging function, a contact device 46 having a convex-shaped surface 62 allows efficient compression of the skin during contact. Compression of the dermis 58 located near the surface 62 of the contact device decreases the distance between this region and the papillae; depending on the force applied, the distance may be decreased by up to several millimeters. Because the radiation field 38' is scattered and correspondingly attenuated during propagation through the dermis, compression of the skin results in bringing more light to the deep portions of the hair follicles for more efficient light-induced heating of the papilla. In addition, compression of the dermis by the contact device using a pressure greater than the patient's blood pressure forces light-absorbing blood out of the irradiated region (indicated during treatment by a whitening of the skin in the pressurized region). This reduces absorption of the optical field, resulting in more efficient delivery of light to the follicular target regions. Pressure applied using a contact device having a convex surface results in a relatively uniform displacement of blood from the skin region. A contact device having this shape is therefore preferred to a flat device, which tends to produce regions having center portions which are not entirely blood-free.

[0029] In alternate embodiments, the contact device may be mounted in the housing in a spring-loaded fashion so that it may be forced against the skin surface with an adjustable pressure. In addition, in this embodiment, the spring mechanism may be attached to a sensor and readout device so that the exact pressure applied to the skin surface can be accurately monitored and/or controlled.

[0030] When forced against the skin, the contact device 46 allows optical radiation to be coupled into and out of the epidermis. With reference now to Fig. 3B, the refractive index (n_{CD}) of the contact device 46 should be approximately matched to that (n_{EP}) of the epidermis 56, which is approximately 1.55. Because light travelling from one refracting medium (i.e., the contact device) to another (the epidermis) is reflected at the interface 57 separating the two regions by an amount related to the square of the refractive index difference, nearly index-matching allows efficient coupling of the irradiating field into the skin. Thus, a contact device composed of a material having a refractive index near 1.5 or somewhat greater allows the incident irradiating field to undergo minimal reflections (indicated in the figure by the arrow 64) at the epidermis/contact device interface 57. Similarly, as indicated in the figure by the arrows 66, optical fields within the dermis are back-scattered towards the epidermis due to diffuse reflectance. These back-scattered fields contribute to unwanted epidermal heating, and are easily coupled out of the skin using the index-matched contact device 46. This allows minimization of the light-induced damage to the epidermis 56, while allowing effective irradiation of the follicle target sites within the dermis. In preferred embodiments, in order to be substantially index-matched, the contact device is preferably formed of a high-density material such as sapphire ($n_{CD}=1.7$), fused silica ($n_{CD}=1.5$), or similar optically transparent glasses or plastics. In order to provide a convergent field entering the skin and to have the convex shape of the contact device as shown, it is advantageous to use sapphire, the slightly higher index of which facilitates the desired field convergence.

[0031] With reference now to Fig. 3C, in order to conduct heat away from the epidermis, it is additionally preferred that the contact device 46 be composed of a material having a high thermal conductivity (k_{CD}) which is similar to that of the skin. This allows efficient transfer of heat (indicated in the figure by the arrows 68) from the epidermis 56, across the contact device/epidermis interface 57, and into the contact device 46. A high thermal conductivity, in addition, is necessary to minimize local heating effects that may occur at the interface 57, thereby reducing the chance of thermally induced damage or injury to the irradiated epidermis. As will be discussed later, this is particularly important when the contact device is cooled. Ideally, the thermal properties of the contact device and the time the contact device is applied to the skin before irradiation begins allow minimization of heating near the epidermis, but have little effect on heat deposited near the papillae of the hair follicle (shown in the figure as region 70). Materials having high thermal conductivities include sapphire ($K_{CD}=0.083\text{cal} \cdot \text{sec}^{-1}\text{cm}^{-2}\text{Ccm}^{-1}$ along the C axis at 30°C), fused silica ($K_{CD}=0.026\text{cal} \cdot \text{sec}^{-1}\text{cm}^{-2}\text{Ccm}^{-1}$ along the C axis at 30°C), as well as other high-density glasses and plastics.

[0032] In addition, in order to improve both optical (i.e., transmission of back-scattered light) and thermal (i.e., heat conduction) properties at the contact device/epidermis interface 57, it is desirable to apply to the skin a topical liquid or emollient, such as a lotion, water, alcohol, or oil, having a refractive index which is similar to that of the contact device 46 and epidermis. For example, application of an oil having a refractive index between that of the epidermis ($n=1.55$) and sapphire ($n=1.7$) minimizes optical reflection effects at the interface, thereby allowing more efficient transfer of light into the skin region from the contact device and of back-scattered radiation from the skin region. Also, a liquid allows for more efficient transfer of heat by conduction from the skin into the sapphire, thereby reducing the

degree of damage or injury to the epidermis.

Optical properties

[0033] The temporal and spatial distribution of intensity for the irradiating optical field inside the skin ultimately determine the amount of heat deposited into the target regions of the hair follicle; these properties therefore can be selected and/or adjusted to optimize the hair-removal process. In particular, properties which affect the hair-removal process include the pulse energy, pulse duration, repetition rate (i.e., the time duration between subsequent pulses), wavelength, energy, exposure spot size, beam convergence as it enters the skin, and mode geometry (i.e., spatial extent and uniformity) of the optical pulse. These characteristics may be selected according to the pigment present in the hair and skin to be irradiated; preferably, each parameter is adjusted so that the temperature at each target site, immediately following irradiation, is elevated to between about 80 and 120°C. Heating the follicle to this temperature leads to permanent damage and subsequent removal.

[0034] Referring now to Fig. 4, the wavelength of the irradiating field is chosen to be resonant with the natural pigment (i.e., melanin) present in the target sites (i.e., the hair shaft, bulge, matrix, and papilla). The absorption spectra of melanin, water, hemoglobin, and oxyhemoglobin shown in the figure indicate the ability of these compounds to absorb optical radiation at different wavelengths; low absorption indicates that light at the particular wavelength will penetrate deeper in the absorbing media. In general, in order to selectively heat the target regions, the wavelength of the irradiating field is chosen to match the absorption spectrum of melanin, which basically absorbs light from about 200nm, to 1200nm; conversely, the wavelength is mismatched to the absorption spectra of compounds contained in the skin, such as water and hemoglobin. Light having wavelengths between 680nm and 1200nm, a range indicated by the arrow 70 in the figure, is effectively absorbed by melanin while being relatively transmitted by both hemoglobin and water, and therefore can be used for selective heating of pigmented hair surrounded by white or lightly tanned skin. In particular, light in the range of 680nm to 900nm or 1000nm to 1200nm is preferred, as this radiation is strongly absorbed by melanin, and will not be absorbed by the bands present in water and in oxyhemoglobin near 950nm. For patients with less melanin present in the hair follicles (e.g. with auburn or light brown hair), the shorter wavelengths in this region are preferable because of the higher absorption coefficient of melanin. In addition, other light-attenuating effects besides absorption, e.g., scattering of radiation, are also wavelength-dependent, and should be considered during selection of the optical field's wavelength. For example, in human skin, the penetration of light is partially determined by the transport scattering coefficient (μ_s), which decreases at longer wavelengths due to scattering in the dermis. For radiation at 1000nm, μ_s is about 10cm^{-1} ; light propagating into the skin from a generally index-matched medium at this wavelength will therefore reach a maximum intensity at about 1mm below the skin surface.

[0035] Sources generating visible or near-infrared light in the preferred range of 680nm-1200nm include diode ($\lambda=800\text{nm}-1000\text{nm}$), Nd:YAG and Nd:YLF ($\lambda=1064\text{nm}$ and 1053nm), Ti:Sapphire and infra-red dye ($\lambda=700\text{nm}-1000\text{nm}$), ruby ($\lambda=694\text{nm}$) and alexandrite ($\lambda=700\text{nm}-850\text{nm}$) lasers. Ruby, Nd:YAG and diode lasers (particular arrays of diode lasers) are preferred as these sources are commercially available, well-categorized, and can be manufactured on a small scale. Light sources of this type can be incorporated into compact hair-removal devices which, in turn, can be easily manipulated by the operator during hair-removal procedures.

[0036] The duration of the optical pulse can also be controlled in order to vary the heating of the hair follicle. Referring now to Fig. 5A, the optical pulses, indicated by the waveforms 74, 74', preferably have durations 76, 76' which allow the follicle to be heated for short periods of time. The pulse width is controlled to vary the heat conduction during the optical pulse, and thus the damage of the follicle and its immediate surrounding dermis; too little damage results in hair re-occurrence, while extensive damage may produce scarring in the irradiated region. Preferably, the pulse duration 76, 76' is between about 2ms and 100ms.

[0037] The exact pulse duration is dictated by the diffusion of heat in the skin, a process which roughly follows the heat diffusion equation relating the diffusion time t , diffusion distance d , and thermal diffusivity k , as discussed by in Welch, A.J. "The thermal response of laser-irradiated tissue", IEEE J. Quant. Electron. QE-21 (12), 1471-1481 (1984): $t=d^2/4k$ (k for the human dermis is roughly $1.3 \times 10^{-3}\text{cm}^2/\text{sec}$). The time needed for extraction of heat from the epidermis during a laser pulse is approximately 2ms, and the thermal relaxation time for a typical $200\mu\text{m}$ hair follicle is approximately 40ms. For light exposures longer than a few hundred milliseconds, too much thermal diffusion may occur during the exposure period, resulting in either inefficient destruction of the target regions of the hair follicle, excessive dermal damage, or both. Further, since most of the melanin (roughly two thirds) in the epidermis is in the lower portion of the epidermis, heating of the epidermis occurs primarily in the deeper portions thereof, and some time is required for this heat to reach the surface in order to be removed by the contact device 46. Therefore, since this time is at least 2ms, this is the minimum suggested pulse duration, with a longer time, preferably at least 5ms, being suggested to minimize epidermal damage. Further, depending on the laser utilized, each pulse could be in the form of a single continuous pulse as shown in Fig. 5A or in the form of a train of closely spaced pulses of shorter duration, the space between such closely-spaced pulses being much shorter than 5ms.

[0038] For a given fluence, the intensity of the optical field is inversely related to the pulse duration; thus, when the pulse duration is below about 10 μ s, large optical intensities may result in undesirable modes of damage to surrounding skin regions. In addition, short pulses may result in localized heat-induced "explosions" in the follicle which cause mechanical damage to the skin. In particularly preferred embodiments, the pulse has a duration or pulsewidth of about 2ms-100ms. During this time period, thermal diffusion takes place over a distance of about 0.05mm to 0.3mm; damage confined to about this distance results primarily in destruction of the irradiated hair follicles, with little or no damage to the surrounding skin.

[0039] Optical pulses having well-defined and adjustable durations may be generated using known techniques. For instance, intra-cavity modulation of the light field using electro or acousto-optic Q-switching devices allows generation of pulses having temporal profiles which are typically Gaussian in shape. Pulses made using these methods are typically too short, however, having durations in the sub-microsecond range. Normal-mode pulses produced by flashlamp excitation of ruby, alexandrite, Ti:sapphire, or Nd:YAG lasers are preferred because these typically are high-energy pulses in the 0.1ms-10ms pulse duration region. Alternatively, a continuous (i.e., time-independent) optical field emitted by a laser can be externally modulated using, for example, a mechanical shutter or electro-optic gate. Modulation using external methods allows the pulse width to be easily varied from a few hundred microseconds to several hundred milliseconds. Pulses generated using external modulation may also have "square wave" temporal profiles (as shown in Fig. 5A) which allow a more uniform optical field to be applied to the region of interest. However, external modulation is not used for currently preferred embodiments.

[0040] When a contact device is used to deliver the optical pulse, a time delay preferably exists between the time at which the contact device contacts the skin surface and the arrival of the pulse. This allows the entire epidermal layer 56 to be cooled significantly prior to irradiation, thereby increasing its damage threshold. Pain and damage to the epidermis are thus reduced and are further minimized by continuing to cool contact device 46 during irradiation so that heat continues to be removed from the epidermis. However, heating at lower levels where destruction of the follicles, and in particular the bulge and papillae thereof, is desired is not affected by the cooling performed either before and/or during irradiation.

[0041] In addition, the time duration between optical pulses (indicated in Fig. 5A by the arrow 78) may be adjusted in order to control the total amount and rate on average of heat deposited into the irradiated region. If repetitive illumination is required for destruction of the follicle, this time period is preferably constant and lies between several seconds and a few hundred milliseconds. Alternatively, for "single shot" illumination, this time period is selectively controlled by the operator. In this case, a single laser shot is delivered to the region of interest, and then the region is inspected by the operator for damage. If more radiation is required, additional laser shots can then be delivered to the region. Otherwise, the irradiation unit is translated and used to treat a separate region.

[0042] The spatial extent of the optical field is chosen to allow multiple hair follicles to be irradiated with a single laser shot. In addition, larger spot sizes are preferred because attenuation along the beam axis within skin due to scattering decreases as the beam radius, R, increases. Thus, wide-area beams allow more efficient delivery of optical radiation to the deep target sites. Referring now to Fig. 5B, the width 80 of the spatial profile 82 of the irradiating beam at the surface of the skin is preferably on the order of, and preferably much greater than, the depth of the target to be irradiated. Most preferably, the beam diameter is at least 8mm. The area of the irradiating field is preferably between about 0.5cm² and 2cm², and is most preferably between 0.75cm² and 1cm². Because the beam is preferably converged, the spatial profile will be condensed as a function of depth before reaching a waist at a depth defined by optical scattering in the dermis. Preferably, as shown in Fig. 5B, the intensity across the beam diameter is roughly constant in order to provide a substantially uniform irradiating field.

[0043] Referring now to Fig. 6, following illumination, the intensity distribution of optical radiation (i.e., the y axis in the figure) as a function of skin depth (i.e., the x axis) is calculated using Monte Carlo-based computer simulations. The distribution is a function of the beam's spatial profile, the optical properties of the medium in contact with the skin. Although the plotted data is based on a computer simulation, and is thus only an approximate, the x axis units are estimated to be about 500 μ m per tick mark. The first curve 90 shows the skin depth-dependent properties of an optical field originating from a small, collimated spot of 800nm light in air. In this case, the majority of the optical intensity is distributed near the surface of the skin (indicated by the "0" point along the x axis), with the intensity dropping off rapidly at larger depths. A larger, collimated spot originating from air (curve 92) has a more evenly distributed skin depth-dependent intensity, although the majority of the light is still concentrated near the skin surface. Delivering a large, collimated radiation spot from a material having a refractive index of 1.5 (curve 94) results in a relatively uniform optical intensity in the first millimeter or so of the skin; at larger depths, this intensity starts to tail off with a relatively slow time constant. Finally, in the preferred embodiment, a large, spatially converging optical field from the n=1.5 refracting material has an intensity at the skin surface which increases to a maximum after propagating about a millimeter into the skin. The intensity then attenuates as a function of skin depth with a time constant slower than that exhibited by the curve 94. Thus, a field of this type can be used to effectively heat the target sites of the follicle, with reduced heating of the skin at the surface, thus reducing heat injury to the skin.

[0044] In the case where the illuminating laser generates a beam having a diameter less than the preferred values, it may be necessary to expand the beam prior to delivery to the irradiating unit. This may be done with conventional telescoping optics, e.g., two-lens systems configured to first expand and then collimate the emitted beam. Alternatively, as shown in Fig. 2A, the irradiating field may be coupled into an optical fiber and then delivered to the irradiating unit. In this case, the emerging field is naturally dispersed due to the waveguide nature of the fiber, and is then collected by a collimating lens. Displacement of the lens from the fiber tip allows the irradiating beam's profile to be increased to the desired amount.

[0045] The fluence of the optical field will be varied according to the degree of pigmentation in the patient, and is preferably between about 10J/cm² and 200J/cm² for each pulse; patients with darker hair will require lower fluence than patients with lighter hair. Most preferably, the pulse fluence of the irradiating field for pulses of about 1ms duration is between 30J/cm² and 50J/cm². As described herein, in all cases, the fluence is adjusted in order to heat the target regions to the desired temperature of approximately 80°C to 120°C. Moreover, the level of fluence may be increased as the pulse duration is increased in order to compensate for less efficient heating of follicles due to heat conduction during long pulses. It may be necessary to increase or decrease the optical fluence in order to heat the hair follicle to the desired temperature if the wavelength of the irradiating light field does not lie in the preferred spectral regions (i. e., 680nm-900nm or 1000nm-1200nm). In addition, in cases where the laser output is below the desired optical fluence, it may be necessary to amplify the individual pulses prior to irradiating the skin. Optical amplifiers, such as external optical cavities, may be used for this purpose.

[0046] Table 1, shown below, lists the preferred parameters of the optical fields used for hair removal. The value of each parameter depends on the amount of hair in the region of interest, the degree of pigmentation of the hairs, and the pigmentation of the surrounding skin of the patient.

Table 1 -

Preferred Optical Field Parameters		
parameter	range	preferred values
wavelength	680nm-1200nm	680nm-900nm, 1000-1200nm
pulse duration	50μs - 200ms	2ms-100ms
beam area	>0.5cm ²	0.7cm ² -1.0 cm ²
pulse energy	10J/cm ² -200J/cm ²	30 - 50 J/cm ²
optical coupling	external n≥1.4	n=1.5 to 1.7
beam convergence, at skin surface	collimated or convergent	f#0.5-2

[0047] The invention will now be further described with reference to the following examples.

Examples

[0048] In order to demonstrate the efficacy of a hair-removal device according to the invention, in vitro black-haired dog skin was exposed to light from the normal mode of a ruby laser at $\lambda=694\text{nm}$ with a pulse duration of 270μs and optical fluences of 40J/cm², 71J/cm², and 160J/cm².

[0049] The spatial extent of the beam (8mm diameter at the skin surface) allowed irradiation of approximately 100 hairs with a single laser shot. Following irradiation, each skin region was examined histologically. Examination revealed that at the highest fluences, dermal damage consistent with scarring of the skin was evident, indicating that at the highest fluences, light-induced thermal damage was not selective to the hairs. In contrast, at the lower fluences, and particularly at 40J/cm², localized follicular damage was observed, with no noticeable damage occurring in the neighboring skin regions or dermis between hair follicles.

[0050] In a separate set of experiments, in order to show that the temperature increase within the irradiated hair is dependent on the degree of pigmentation, fresh human hair and skin samples having different colors were exposed using the hair-removal method described herein. The light source for all experiments was the ruby laser described above. Emitted light was first coupled into an enclosed beam-steering device containing several mirrors coated to have high reflectivities at 694nm, and then delivered to an irradiating unit similar to that shown in Fig. 2B. The unit included a 5-cm plano-convex glass lens positioned at the proximal end of a water-cooled plexiglass housing. A sapphire contact device shaped as a 1-cm focal length lens was disposed at the distal end of the contact device, with the convex side touching the skin to allow compression during exposure as described above. Human skin was irradiated with an 8mm

diameter beam by pressing the cooled (4°C) contact device against the skin region of the patients, and then delivering a single laser shot. Each shot typically resulted in the simultaneous exposure of about 10 hairs.

[0051] The skin and hair of six adult patients having hair color ranging from red to black was irradiated and then observed. In each patient, eight treatment sites, each having an area of 10cm², were irradiated. In order to monitor destruction of the papilla, sites 1-4 were wax-epilated prior to exposure to laser light, while sites 5-8 were shaven prior to exposure. Each site then received an optical fluence of either 28J/cm², 42J/cm², or 57J/cm². Patients were seen in follow-up examinations one month and three months (and for some patients also one year) after exposure. As seen from the photographs of the exposed regions shown in Fig. 7 (i.e., regions A-C), hair regrowth after three months was minimal or non-existing in all cases compared to the shaved-but-untreated region (Region D), clearly indicating permanent damage to the hair follicle. In the figure, sites A-C were treated with decreasing energy from the laser. It is clearly evident that hair removal is relatively less pronounced in region C, treated with a fluence of 27J/cm². Region D, the control region, was shaven at the same day regions A-C were treated. In addition, histological specimens obtained from the treated sites revealed that damage occurred exclusively to the hair follicle, while the surrounding dermis was essentially spared. There was statistically significant loss of hair for all of the subjects in the laser-treated sites compared with unexposed, shaven control sites. At one year later, there was also significant permanent hair loss without any scarring.

[0052] A separate set of experiments permitting measurement of the time-dependent temperature characteristics of hair and skin samples were conducted using a pulsed photothermal radiometry (PPTR) apparatus. In these experiments, the ruby laser described above was used at lower fluences to provide optical pulses having an energy allowing heating, but not destruction, of the follicles. Output from the laser was focussed onto the samples of human hair and skin to provide a uniform excitation field. A New England Research, Inc. black-body radiation detector containing an amplified, liquid nitrogen-cooled HgCdTe detector was used to monitor time-dependent characteristics of the sample temperature, and a Gentec, Inc. laser energy meter was used to monitor the irradiating pulse. The output from both detectors was then amplified with a compensated 0-10Mhz dc-coupled preamplifier, and then relayed to a digital oscilloscope for recording and storing the data.

[0053] Eight patients having various skin types and hair coloring ranging from red/blonde to black were studied. In general, the PPTR results indicated that following irradiation at 694nm, black hair experienced a larger temperature rise than lighter brown hair, and that both of these specimens experienced higher temperature rises compared to red/blonde hair. In addition, following irradiation, type II skin had a lower temperature rise than type III or type IV skin.

[0054] Referring now to Figs. 8A-8C, in a particular example using a patient with black hair and white skin, time-dependent traces measured using the PPTR apparatus indicate that 400ms after irradiation, both wet and dry black hair experience, respectively, temperature rises of about 7°C and 72°C (Figs. 8A and 8B) from a baseline temperature of 23°C, whereas the surrounding skin (Fig. 8C) undergoes a temperature rise of less than 1°C. The difference in the temperature rise and time-dependent decay characteristics of the wet hair is likely due thermal effects (e.g., the higher heat capacity of wet hair).

[0055] Referring now to Fig. 9, in all cases, the normalized temperature rises (i.e, the ratio of temperature rise to laser pulse energy) in the wet and dry hair follicles were significantly higher than those measured in the skin, indicating selective heating of the follicles. Table 2, shown below, lists the hair and skin types of each patient in the study. The patient numbers in the table correspond to the patient numbers in Fig. 9.

Table 2 -

Patient Hair and Skin Types		
patient	hair	skin type
1	red	II
2	brown	III
3	brown	II
4	gray/black	III
5	gray/Black	III
6	dark brown	III
7	gray/black	II
8	black	III

Other Embodiments

[0056] Fig. 10A illustrates an alternative embodiment of the invention wherein the region 20 is epilated rather than being merely shaved prior to treatment. A fluid solution or suspension 100 containing a chromophore may then be applied to the skin region 20, with the chromophore containing fluid migrating into the empty follicles and filling the follicles. "Capillary action" of the fluid/chromophore into the follicles is desirable and may be enhanced by providing a low surface tension between the fluid and skin, for example by using surfactants or solvents. The excess fluid/chromophore may then be removed from the skin surface by washing, wiping or stripping. During irradiation, the chromophore 100 in the follicle absorbs light and is heated and, along with the heating of the melanin of the follicle itself, results in significant heating of the follicle to destroy the portions thereof, including the bulge and the papilla, required to prevent regrowth of hair. The chromophore therefore must absorb light at the wavelength or wavelengths used for irradiation. Suitable chromophores might include a carbon particle suspension or a dye such as methylene blue or indocyanine green. Melanin itself in liposomal form might also be used. Since the chromophore is only in the follicles, this technique maximizes damage to the follicles while minimizing damage to surrounding tissue, and for this reason is a preferred way of practising the invention, especially for those with blond, red, light brown or other light colored hair. Except for the differences indicated above, this embodiment of the invention operates in the same manner described for earlier embodiments, including the cooling of contact device 46, the deformation of the skin in the region 20, and the preferred optical irradiation, with the exception that lower frequency may be allowed when using the chromophores.

[0057] Fig. 10B illustrates another alternative embodiment of the invention wherein the contact device or applicator 46' is modified so as to simultaneously expose both sides of a skin fold. This further increases the relative delivery of light to the deep portion of the follicles. In Fig. 10B, the contact device has for example an opening or slot 110 in the face of the applicator into which the area 20 of the skin may be drawn by for example vacuum or suction being applied to line 112 leading into the top of slot 110, the skin in slot 110 being formed into a fold 113. Radiation may be applied through a fiber-optic bundle 114 which divides to apply the radiation to lenses 116 on either side of slot 110. Cooling water may be flowed over the surfaces of lenses 116 through a line 118. Alternatively, two applicators similar to those shown for example in Fig. 2A or 2B can be positioned on opposite sides of a skin fold formed by clamping the skin region therebetween or by other suitable means.

[0058] The advantage of folding the skin as discussed for the above embodiments is that radiation is applied to a relatively thin section of skin from both sides. Thus, the papilla of a given follicle may be receiving radiation not only from the lens 116 on the side of slot 110 where the follicle is located, but also some radiation from the lens 116 on the opposite sides of the slot. Thus, energy applied to the papilla of each follicle is increased without increasing the energy at the surface, thus facilitating hair removal with less pain and injury. By making the slot 110 relatively narrow, pressure is applied to the skin on both sides of the slot, the skin being compressed between the walls of the slot. The advantages of compressing the skin, including removing blood therefrom and reducing the distance from the skin surface to the papilla, are thus also achieved by this embodiment of the invention. Clamping to form the fold would also apply pressure to the skin.

[0059] It may also be possible to utilize the apparatus of this invention for short term hair removal, the device serving as for example a razor which might provide a shave lasting for perhaps one to two weeks. This is achieved by applying the fluid/chromophore to the region which is to be "shaved" which region has preferably been shaved using conventional techniques, but not epilated. In this case the chromophore can only migrate a few millimeters into the follicle, to for example the level of the sebaceous gland. Excess chromophore may then be removed, and the contact device of this invention utilized with relatively low level radiation to heat the chromophore, and destroy the hair surrounded thereby, without substantial damage to either the skin or follicle.

[0060] Further, while cooling water has been shown for the preferred embodiment to cool contact device 46, this is not a limitation on the invention and other cooling techniques may be utilized. For example, a low temperature gas or liquid gas may be passed over the contact device for cooling purposes or the contact device may be sufficiently cooled prior to use so that it can continue to perform the cooling function during irradiation without having a cooling medium passed thereover. Other cooling techniques known in the art may also be utilized.

[0061] Other embodiments are within the scope of the following claims. For example, the contact device may not be cooled or cooling of the epidermis may be performed without an applicator (for example cryogenically). Where an applicator is not utilized, radiation is applied directly to the region of interest after passing through the appropriate optics.

Claims

1. Apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising:

an applicator (18) (46');
a source (12) of optical radiation; and
an optical path (16) (114) from the source of optical radiation to the said surface of the said applicator, which
path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed
through the said surface of the said applicator to the said skin region,

characterised in that the said radiation has a wavelength between 680nm and 1200nm and a fluence of
between 10J/cm² and 200J/cm², and **in that** the duration of the radiation on the said skin region is 50µs to 200ms.

2. Apparatus according to claim 1 in which the duration of the radiation on the said skin region is 5ms to 200ms.

3. Apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle
extending into the skin from a surface, the apparatus comprising:

an applicator (18) (46');
a source (12) of optical radiation; and
an optical path (16) (114) from the source of optical radiation to a surface of the said applicator, which path is
substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed
through the said surface of the said applicator to the said skin region,

characterised in that the apparatus further comprises means (50, 52) (118) for cooling a surface of the
applicator to a temperature below that of the said skin region.

4. Apparatus according to claim 3 wherein the said cooling means (50, 52) (118) cools the said surface of the
applicator (18) (46') below that of the said skin region by an amount which is sufficient in conjunction with selected
radiation to prevent substantial heating of the said skin region with which the applicator is in contact for a selected
depth and not to substantially interfere with heating of the skin in the said region beyond the said selected depth.

5. Apparatus according to claim 3 or 4 wherein the means for cooling (50, 52) (118) is a channel near the said
surface of the applicator (18) (46') through which cooling water is passed.

6. Apparatus according to claim 1, 3, 4 or 5 wherein the said radiation has a wavelength between 680nm and
1200nm, preferably between 680nm and 900nm, and a fluence of between 10J/cm² and 200J/cm², and in that the
duration of the radiation on the said skin region is 2ms to 200ms.

7. Apparatus according to any preceding claim wherein at least the said surface of the applicator (18) (46') is
formed of a material having a refractive index which substantially matches the refractive index of the skin surface
in the said skin region.

8. Apparatus according to any preceding claim in which the applicator (18) (46') comprises a surface adapted to
be in contact with the skin surface in a skin region from which hair is to be removed.

9. Apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle
extending into the skin from a surface, the apparatus comprising:

an applicator (18) (46') comprising a surface adapted to be in contact with the skin surface in a skin region
from which hair is to be removed;
a source (12) of optical radiation; and
an optical path (16) (114) from the source of optical radiation to the said surface of the said applicator, which
path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed
through the said surface of the said applicator to the said skin region,

characterised in that at least the said surface of the applicator (18) (46') is formed of a material having a
refractive index which substantially matches the refractive index of the skin surface in the said skin region.

10. Apparatus according to any preceding claim further comprising an element (42, 46) (116) in the optical path
for converging the optical radiation as it leaves the applicator (18) (46') through the said surface.

11. Apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a surface, the apparatus comprising:

an applicator (18) (46') comprising a surface adapted to be in contact with the skin surface in a skin region from which hair is to be removed;
a source (12) of optical radiation; and
an optical path (16) (114) from the source of optical radiation to the said surface of the said applicator, which path is substantially transparent to optical radiation at a selected wavelength, the optical radiation being passed through the said surface of the said applicator to the said skin region,

characterised in that further comprising an element (42, 46) (116) in the optical path for converging the optical radiation as it leaves the applicator (18) (46') through the said surface.

12. Apparatus according to claim 10 or 11 wherein the said element (42, 46) (116) is a lens.

13. Apparatus according to any of claims 9 to 12 wherein the said radiation has a wavelength between 680nm and 1200nm, preferably between 680nm and 900nm, and a fluence of between 10J/cm² and 200 J/cm², and in that the duration of the radiation on the said skin region is 2ms to 200ms.

14. Apparatus according to any preceding claim wherein the applicator (18) (46') further comprises a housing (48), the said surface being disposed on the housing and having a convex shape and the said optical path (16) (114) passing through the said housing from the source (12) of optical radiation to the said surface.

15. Apparatus according to any preceding claim wherein the said surface of the applicator (46') has a slot (110) formed therein and wherein the optical path (114) leads to at least two opposite sides of the slot and includes means (112) for positioning at least a portion (113) of the said skin region into the slot.

16. Apparatus according to claim 15 wherein the means for positioning includes means (112) for applying vacuum to the slot.

17. Apparatus according to any preceding claim wherein the source (12) of optical radiation is a laser.

18. An applicator suitable for use in practising a method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin, from a skin surface, comprising:

a housing;
a transmitter of optical radiation into said housing;
a surface disposed on the housing having a convex shape and adapted to be in pressure contact with the skin surface in the said skin region;
an optical path through said housing from the transmitter of optical radiation to the said surface which path is substantially transparent to optical radiation at the said selected wavelength;
an element in the optical path for converging the optical radiation as it leaves the applicator through the said surface; and
means for cooling the said surface to a temperature below that of the said skin region.

19. An applicator according to claim 18 in which: the said surface disposed on the housing shaped to contact the skin surface in the said skin region has a slot formed therein; and in which the optical path leads to at least two opposite sides of the slot, and includes means for positioning at least a portion of the said skin region into the slot.

20. An applicator as claimed in claim 19 wherein the means for positioning includes means for applying vacuum to the slot.

21. An applicator according to claim 18, 19 or 20 wherein at least the said surface is formed of a material having a refractive index which substantially matches the refractive index of the skin surface in the said skin region.

22. An applicator according to any of claims 18 to 21 wherein the element is a lens.

23. An applicator according to any of claims 18 to 21 wherein the means for cooling is a channel near the said

surface through which cooling water is passed.

24. Apparatus for the simultaneous removal of a plurality of hairs from a skin region containing the plurality of hairs, each hair being in a follicle extending into the skin from a skin surface, the apparatus comprising:

an applicator which is adapted to be in pressure contact with a portion of the skin surface containing a plurality of hairs in the said skin region, the applicator having a surface in contact with the skin surface, and including a mechanism which cools the said surface of the applicator below that of the said skin region by an amount which is sufficient in conjunction with selected radiation to prevent substantial heating of the said skin region in which the applicator is in pressure contact for a selected depth and not to substantially interfere with heating of the skin in the said region beyond the said selected depth;
a source of optical radiation; and
means for applying the optical radiation from the source to the applicator, the optical radiation being passed through the applicator to the said skin region.

25. Apparatus according to claim 24 wherein the radiation from the source of optical radiation is of a wavelength between 680nm and 1200nm, a fluence between 10J/cm² and 200J/cm² and a pulse duration between 50µs and 200ms.

26. Apparatus according to claim 25 wherein the means for cooling includes a channel near the said surface through which cooling water is passed.

28. Apparatus according to any of claims 24 to 26 wherein the applicator has a surface in contact with the skin surface, the said surface of the applicator having a slot formed therein, wherein the means for applying the optical radiation includes optical paths in the applicator leading to at least two opposite sides of the slot, and wherein the applicator includes means for positioning at least a portion of the said skin region in the slot between the said at least two opposite sides.

29. Apparatus according to any of claims 1 or 3 to 28 wherein the duration of the radiation on the said skin region is 2ms to 100ms.

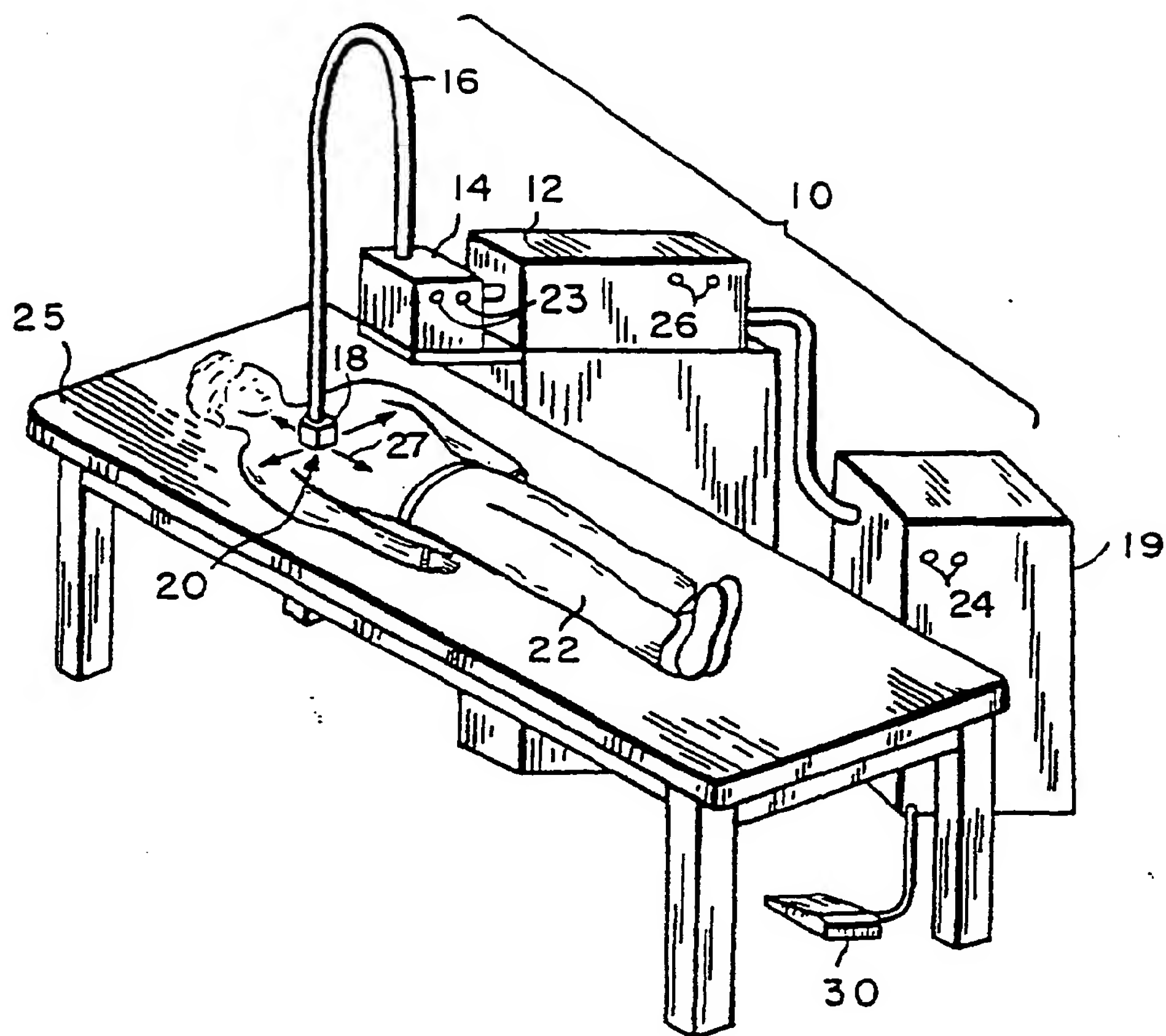


FIG. 1

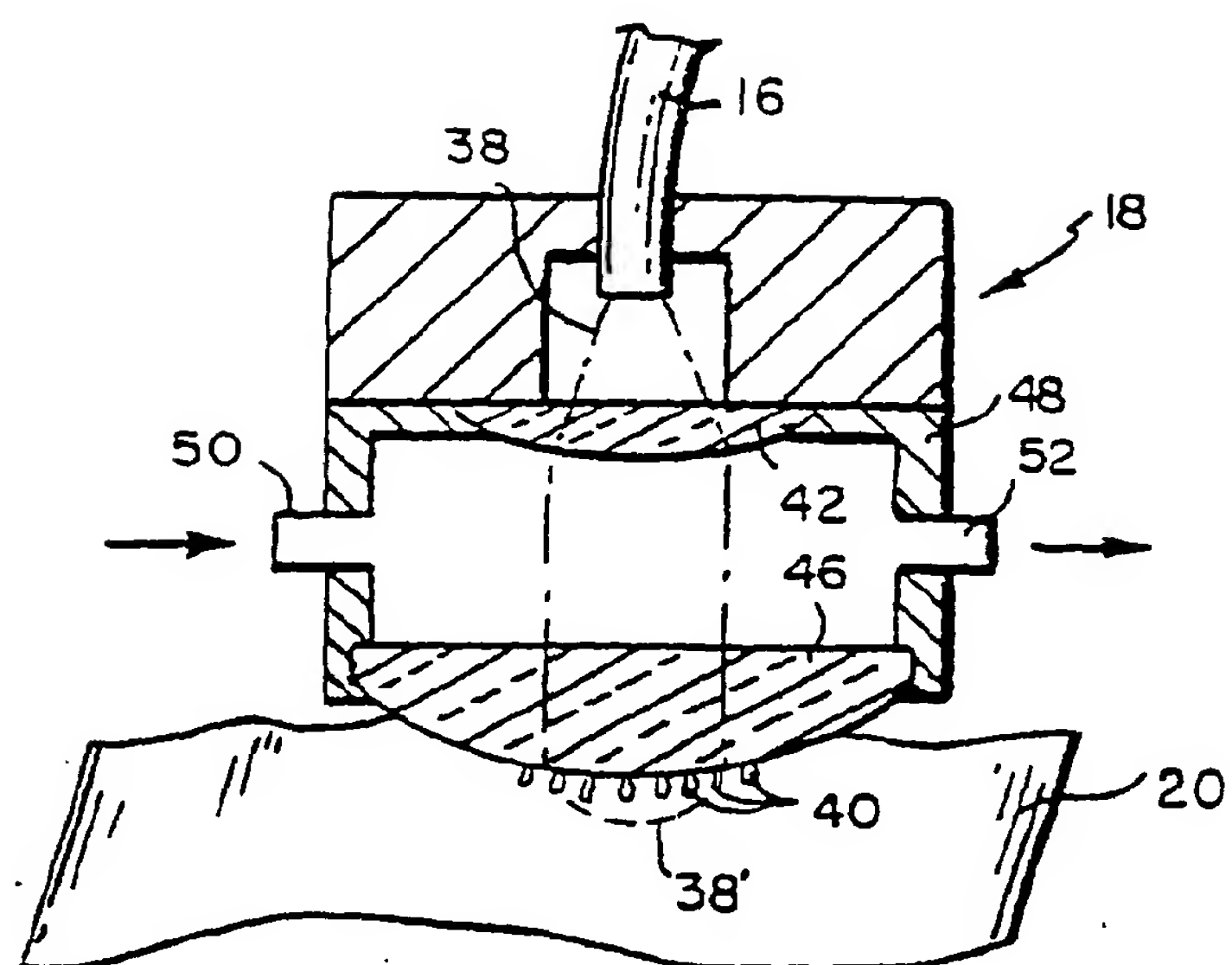


FIG. 2A

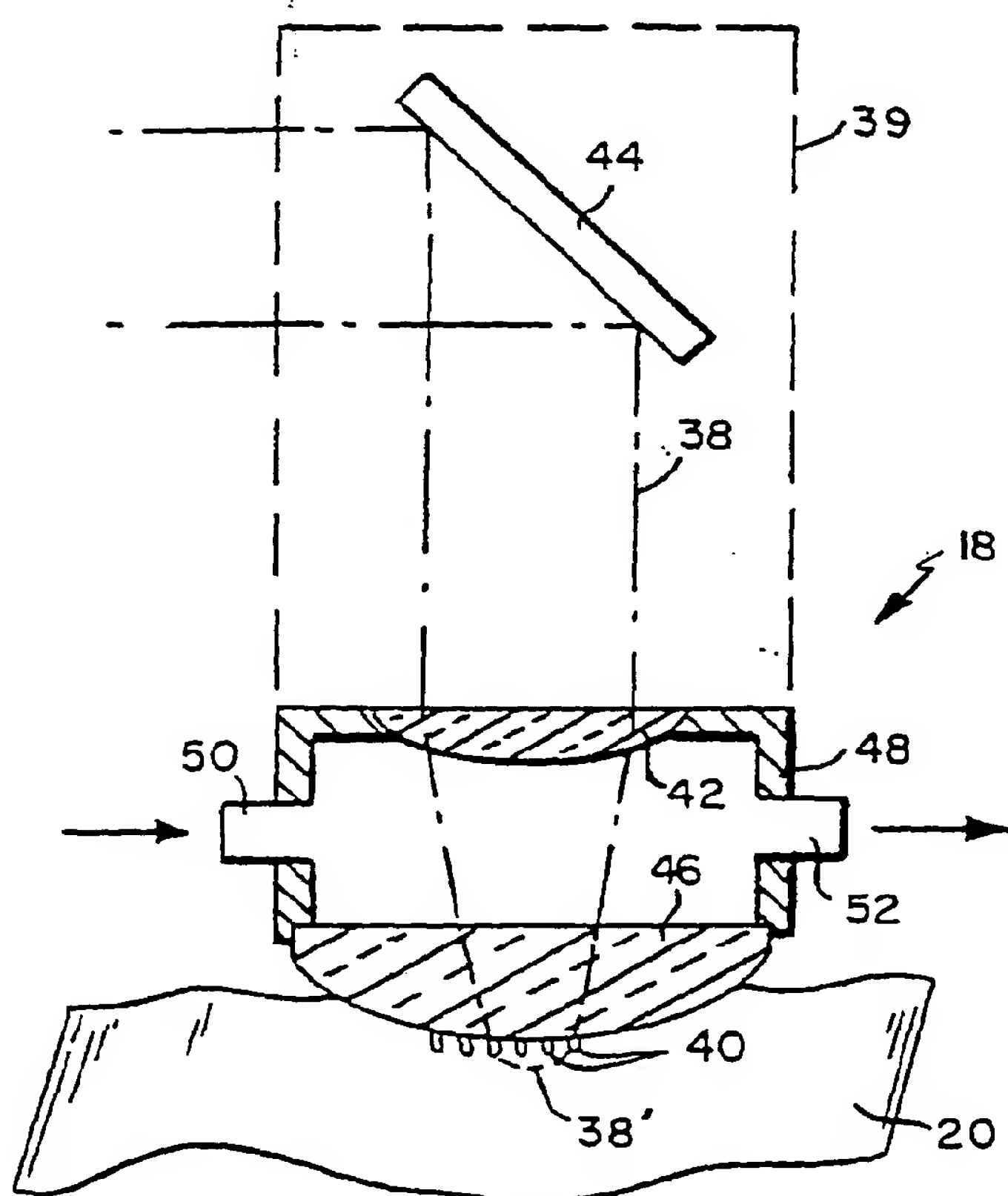


FIG. 2B

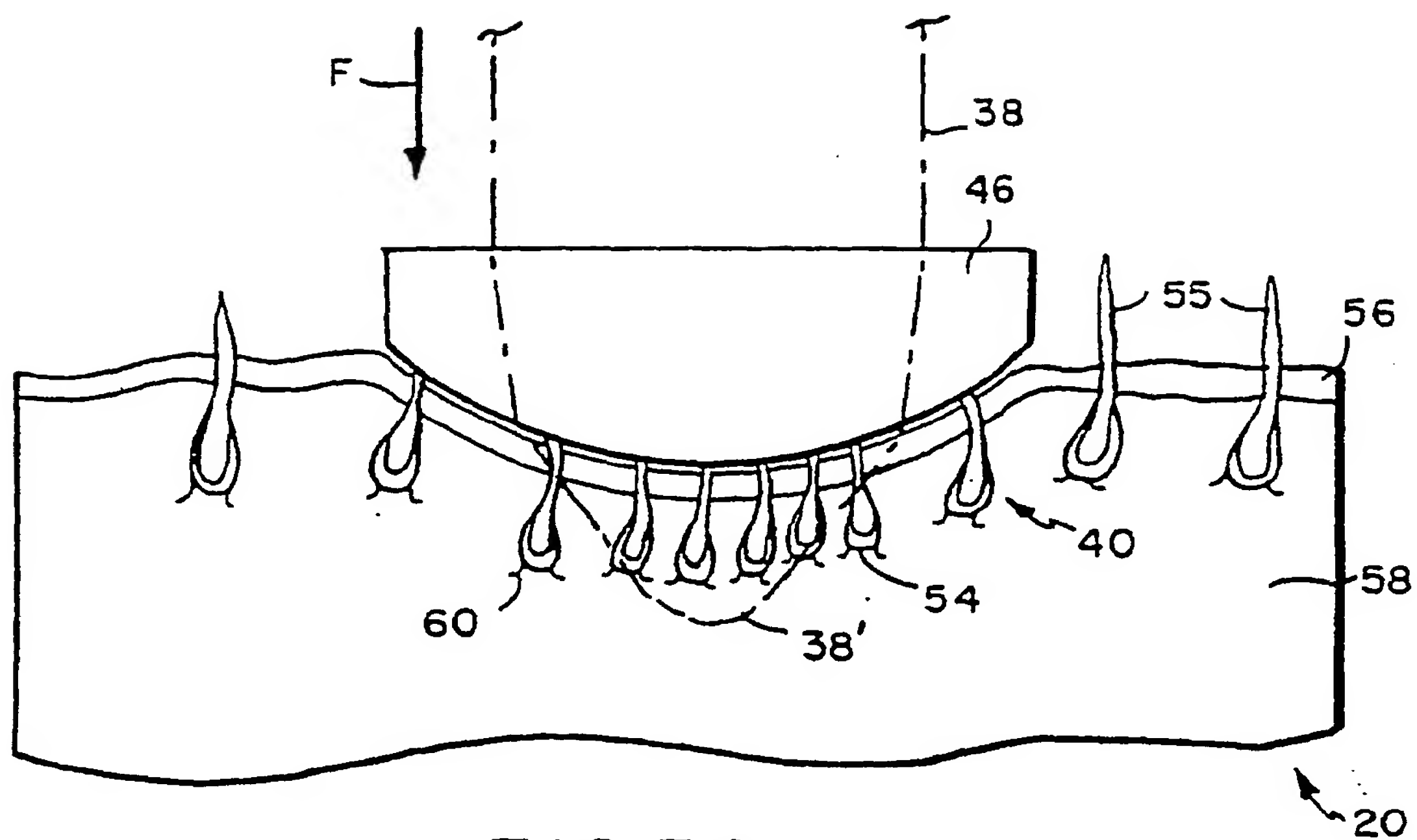


FIG. 3A

FIG. 3B

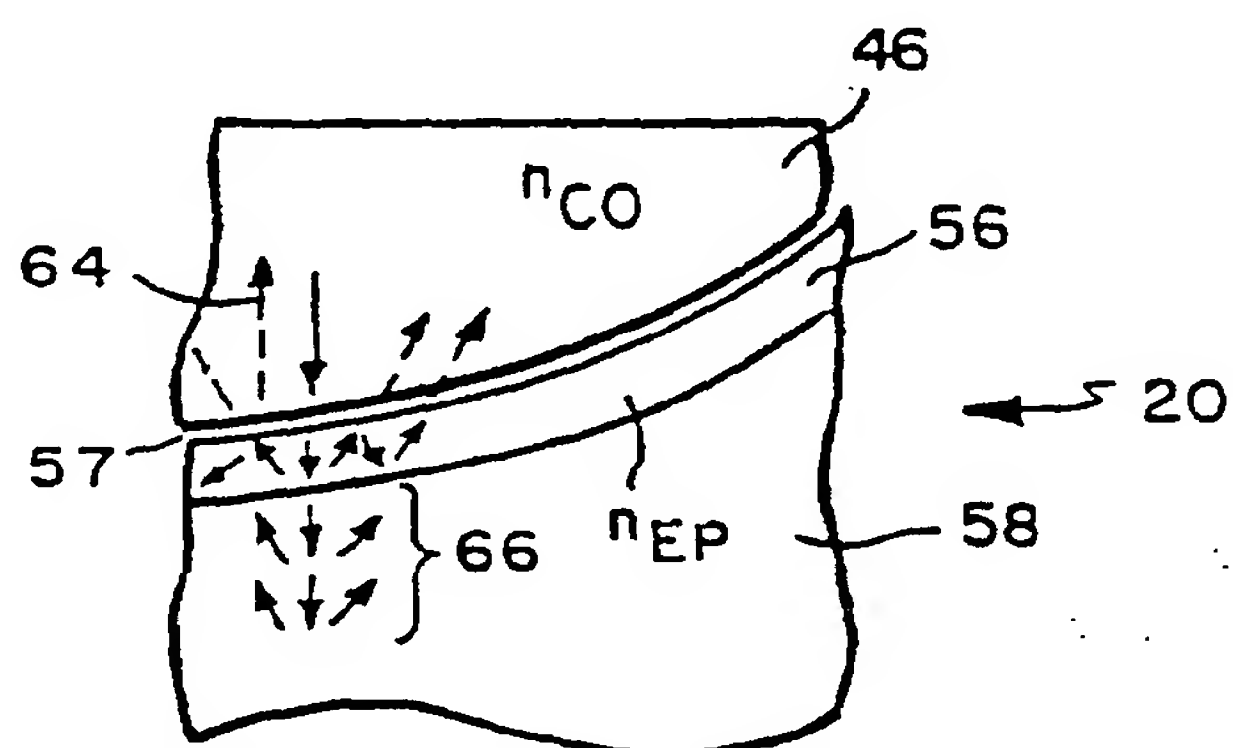
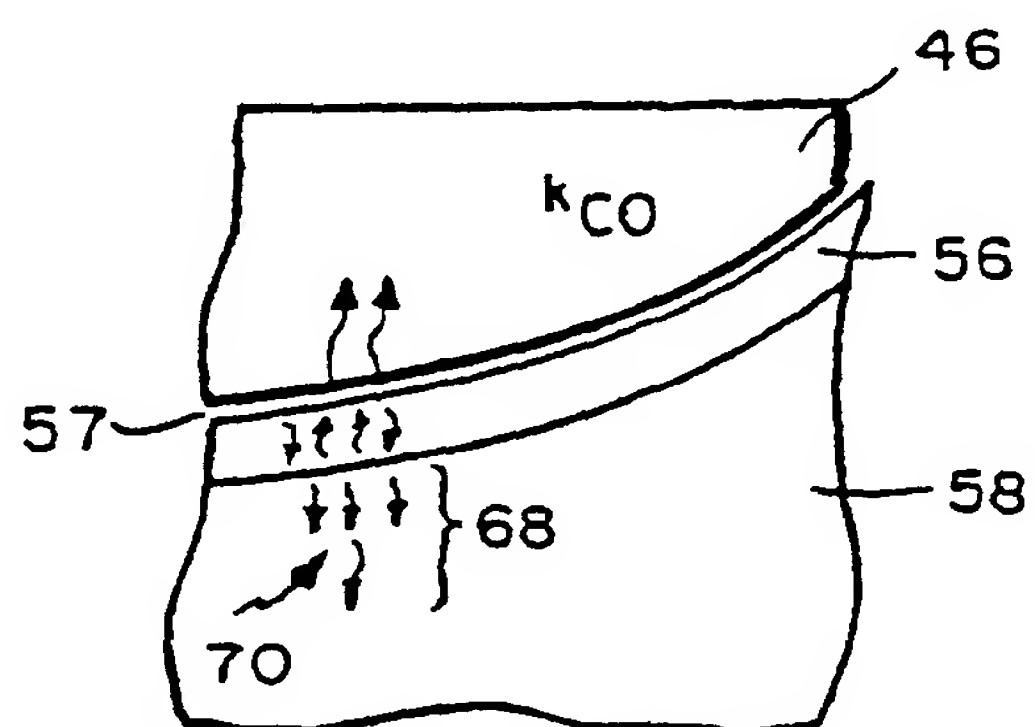


FIG. 3C



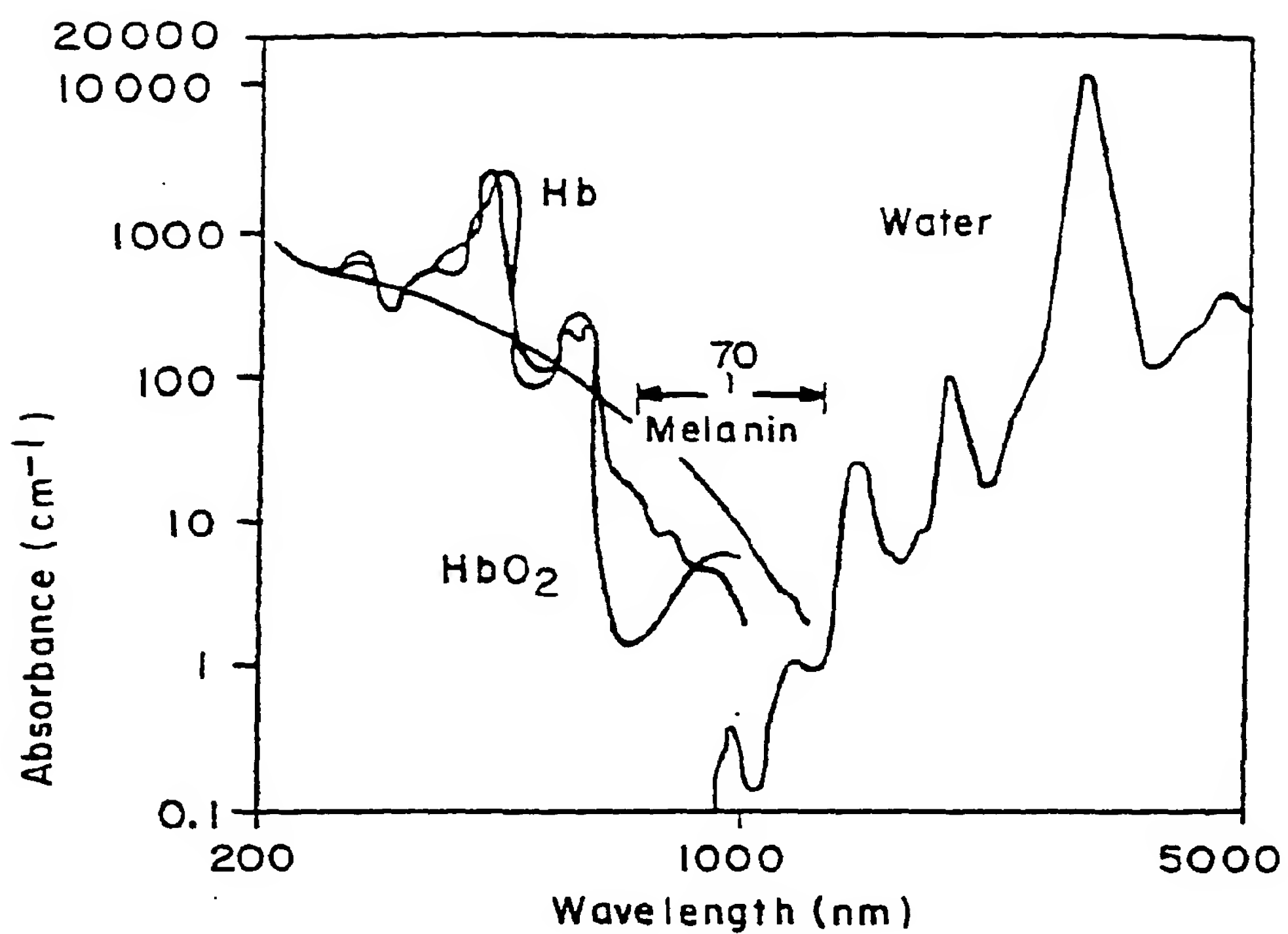


FIG. 4

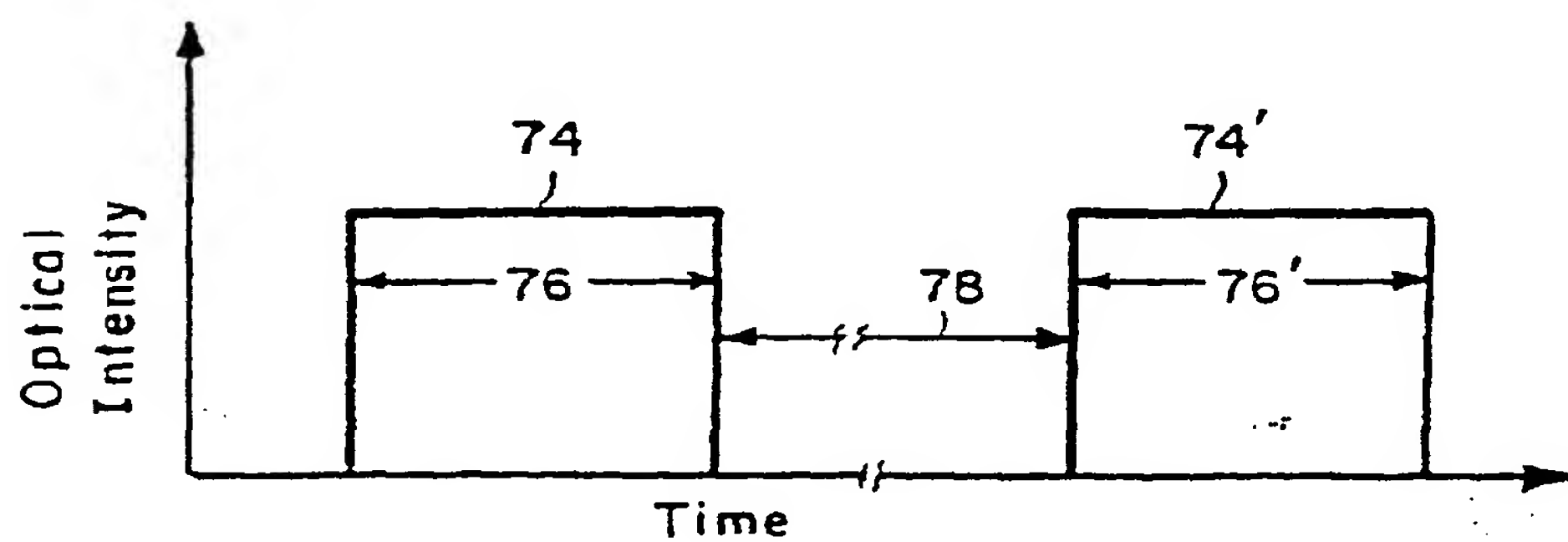


FIG. 5A

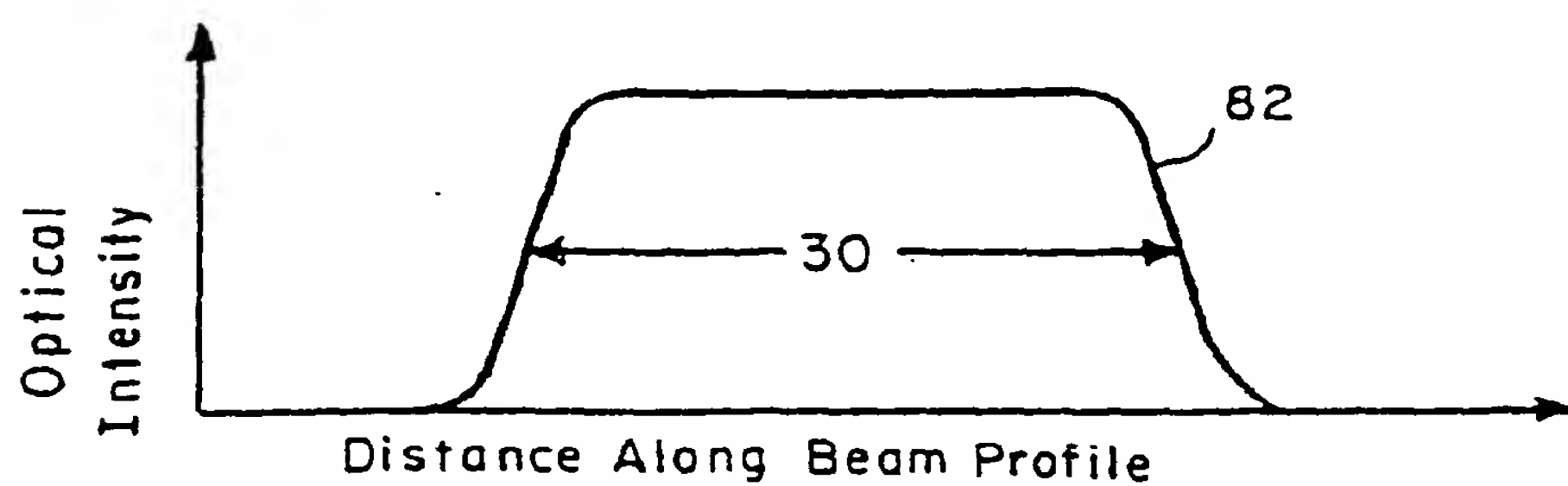


FIG. 5B

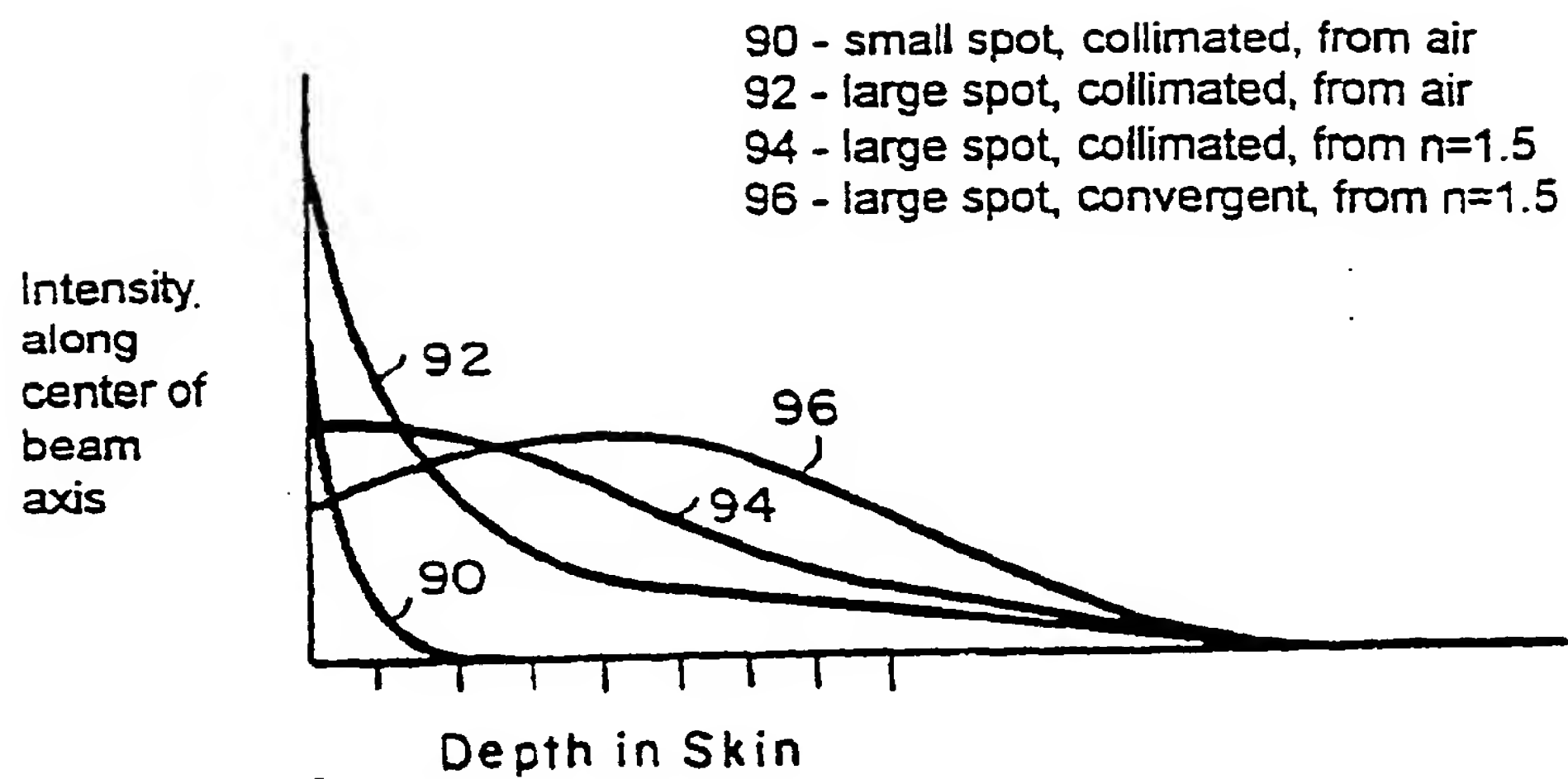


FIG. 6

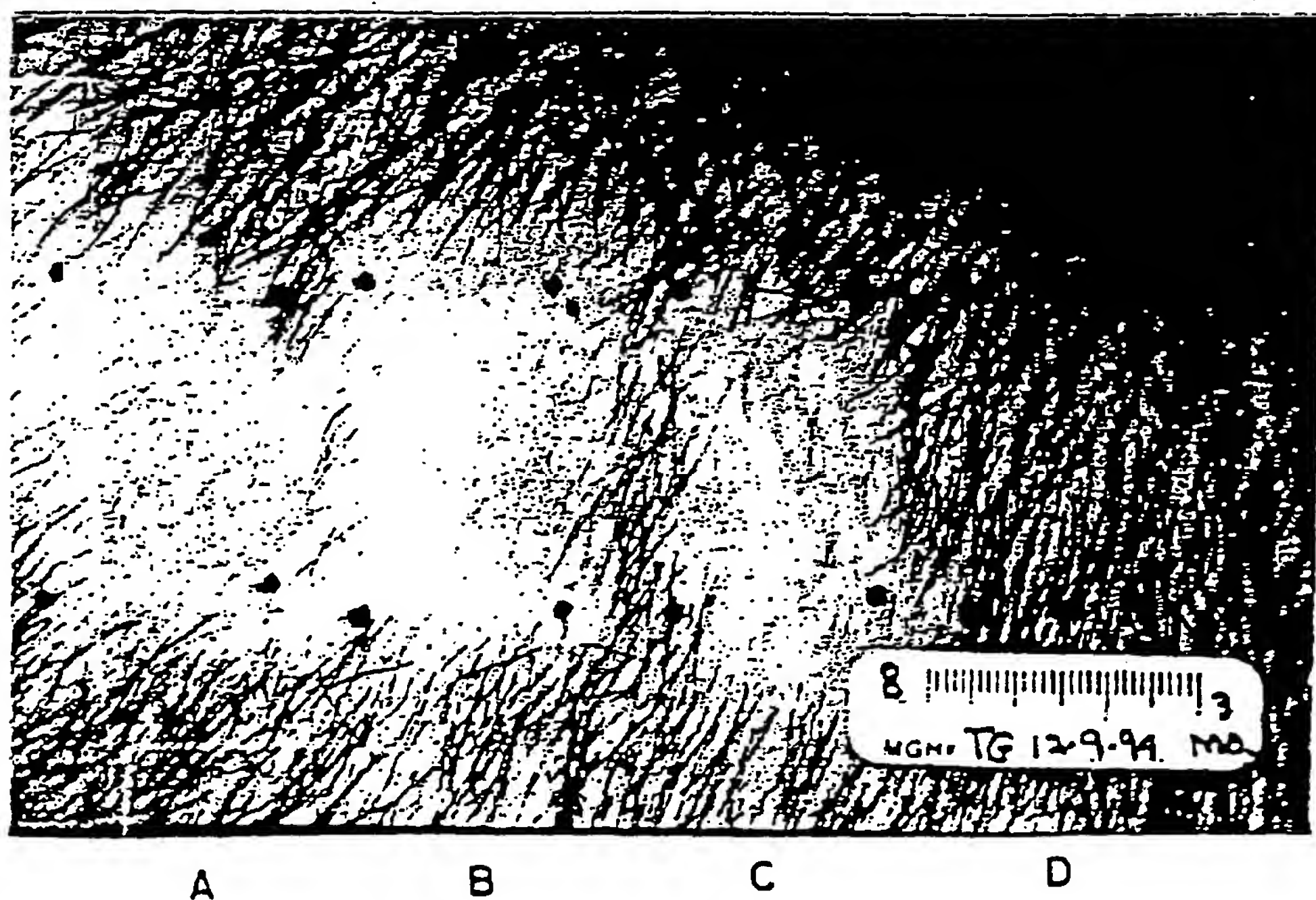


FIG. 7

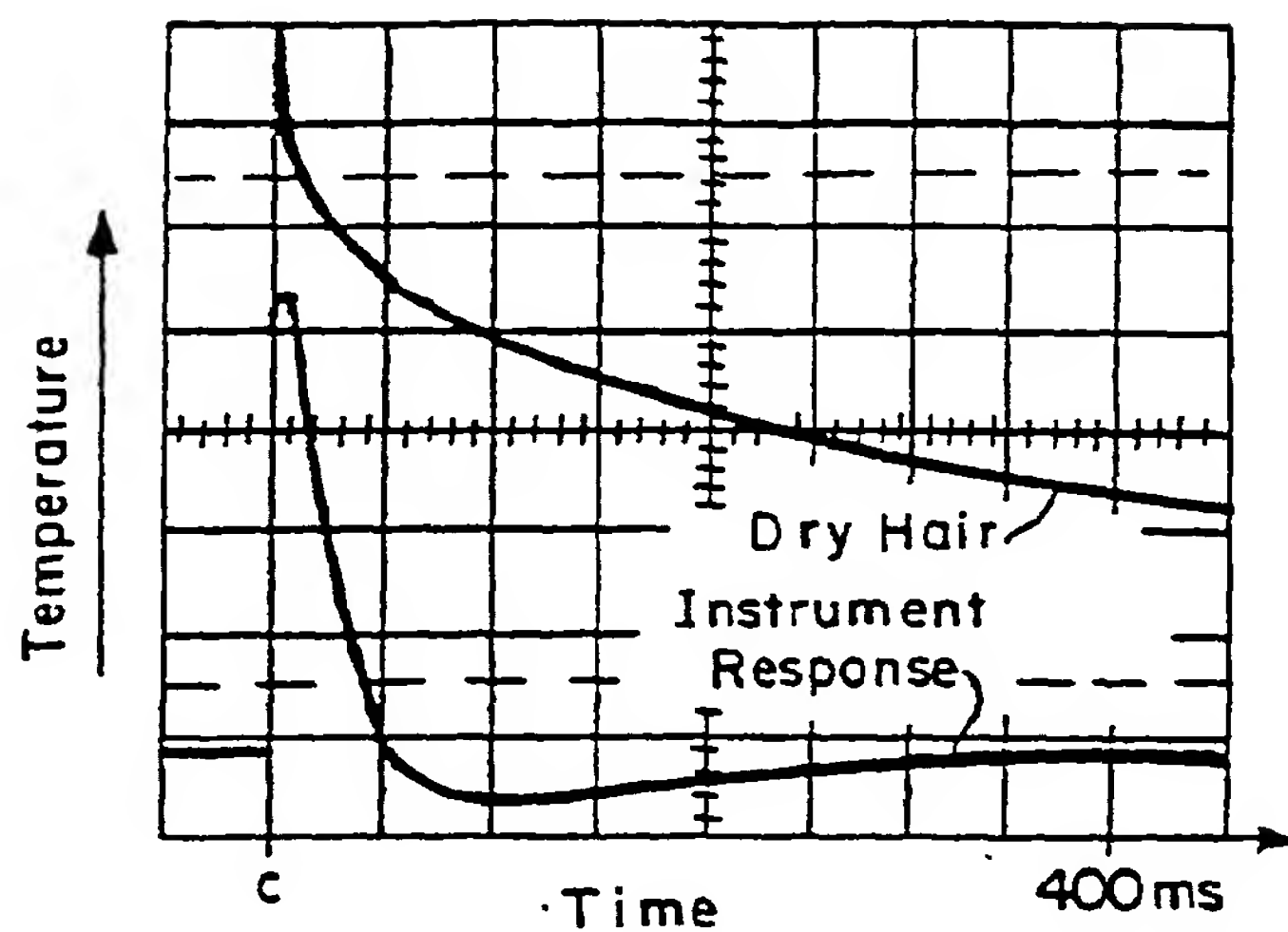


FIG. 8A
(Dry Hair)

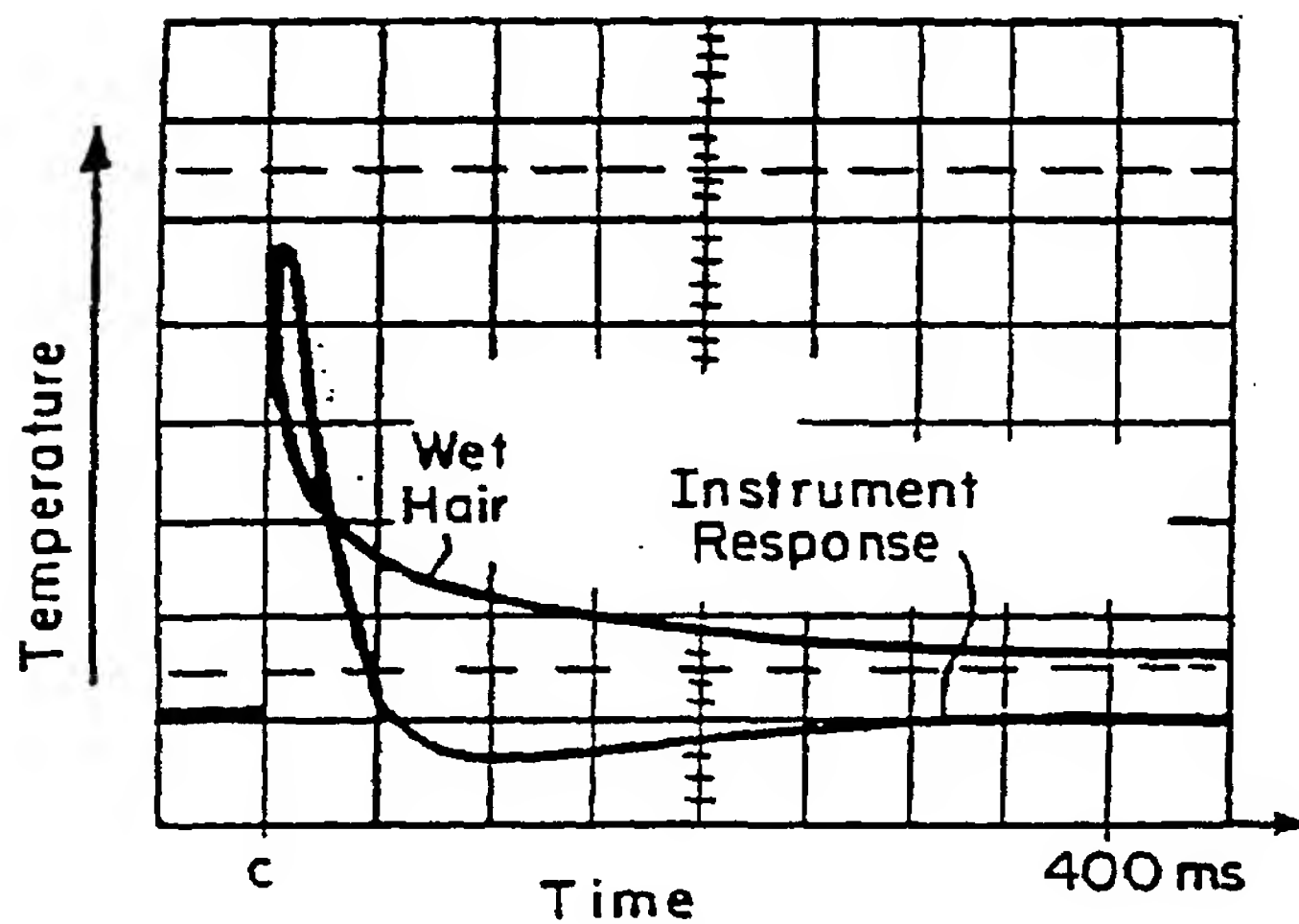


FIG. 8B
(Wet Hair)

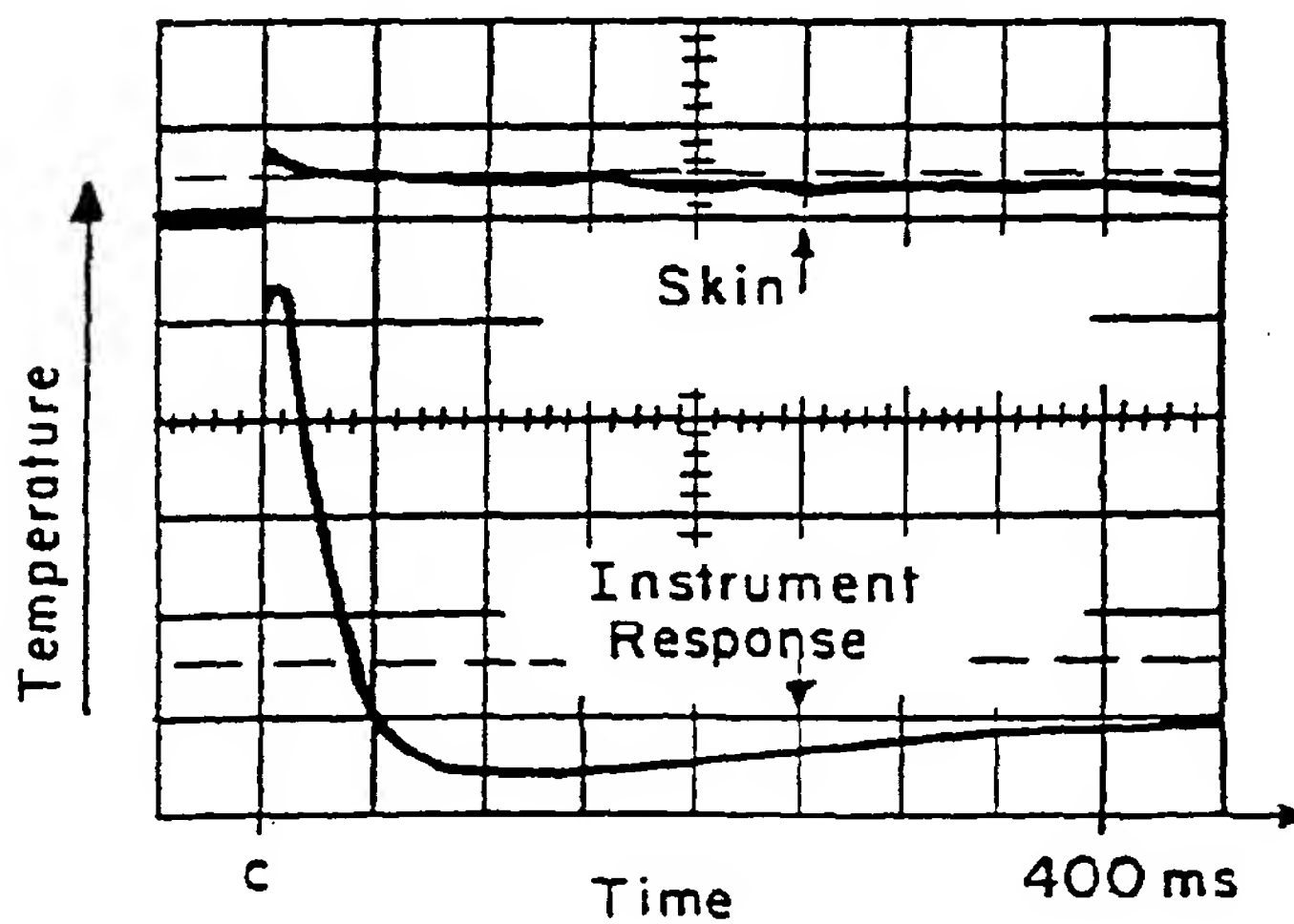


FIG. 8C
(Skin)

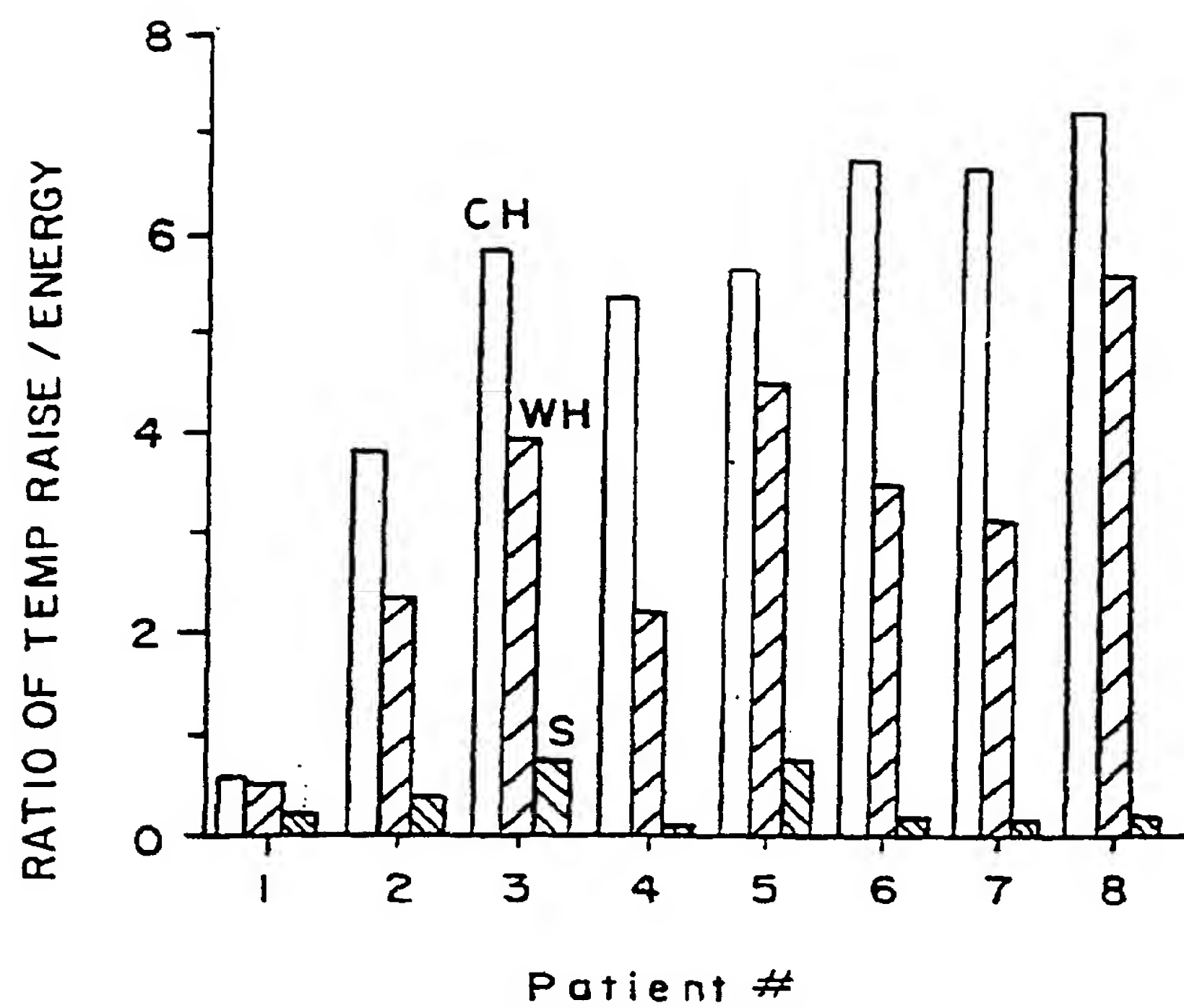


FIG. 9

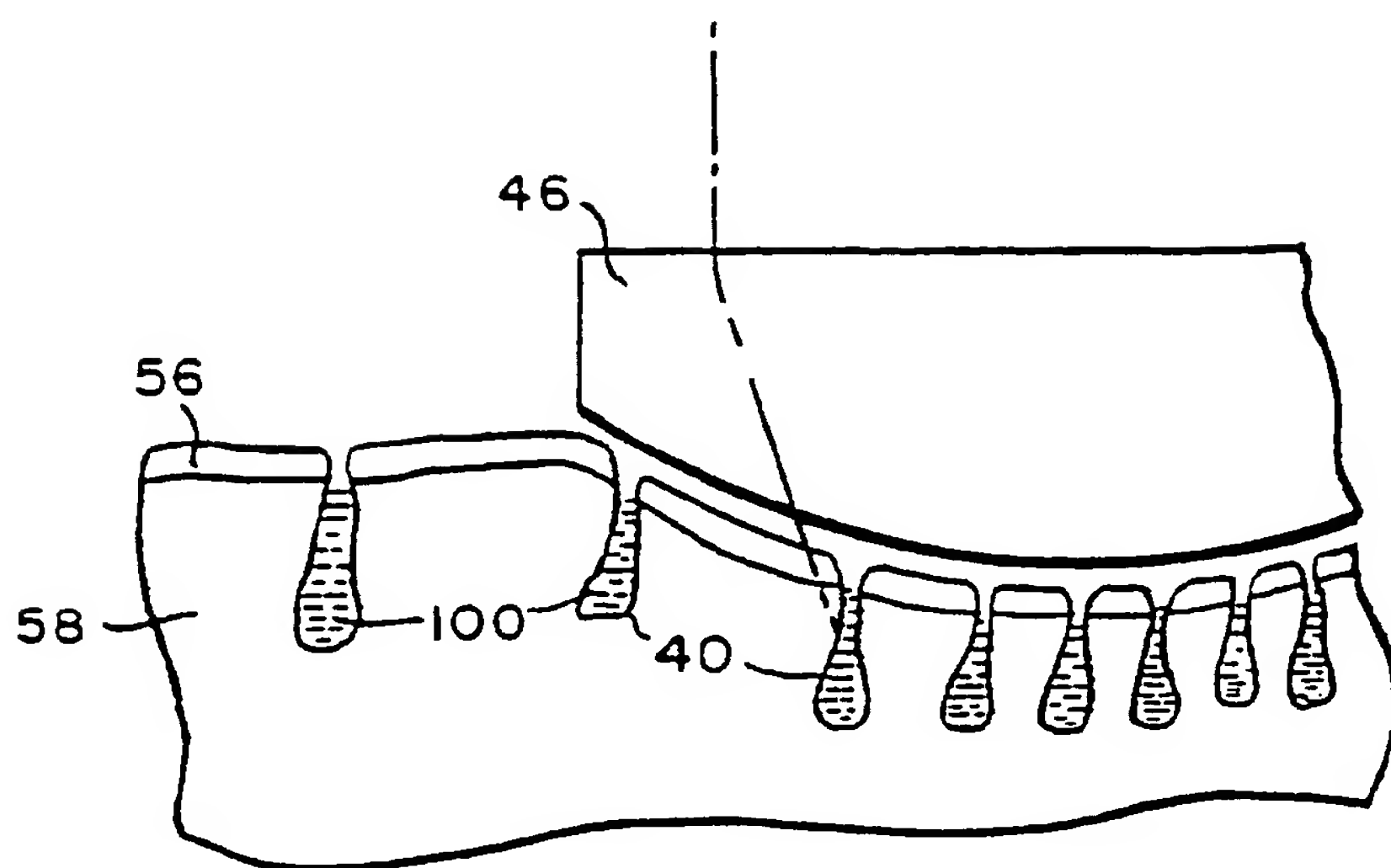


FIG. 10A

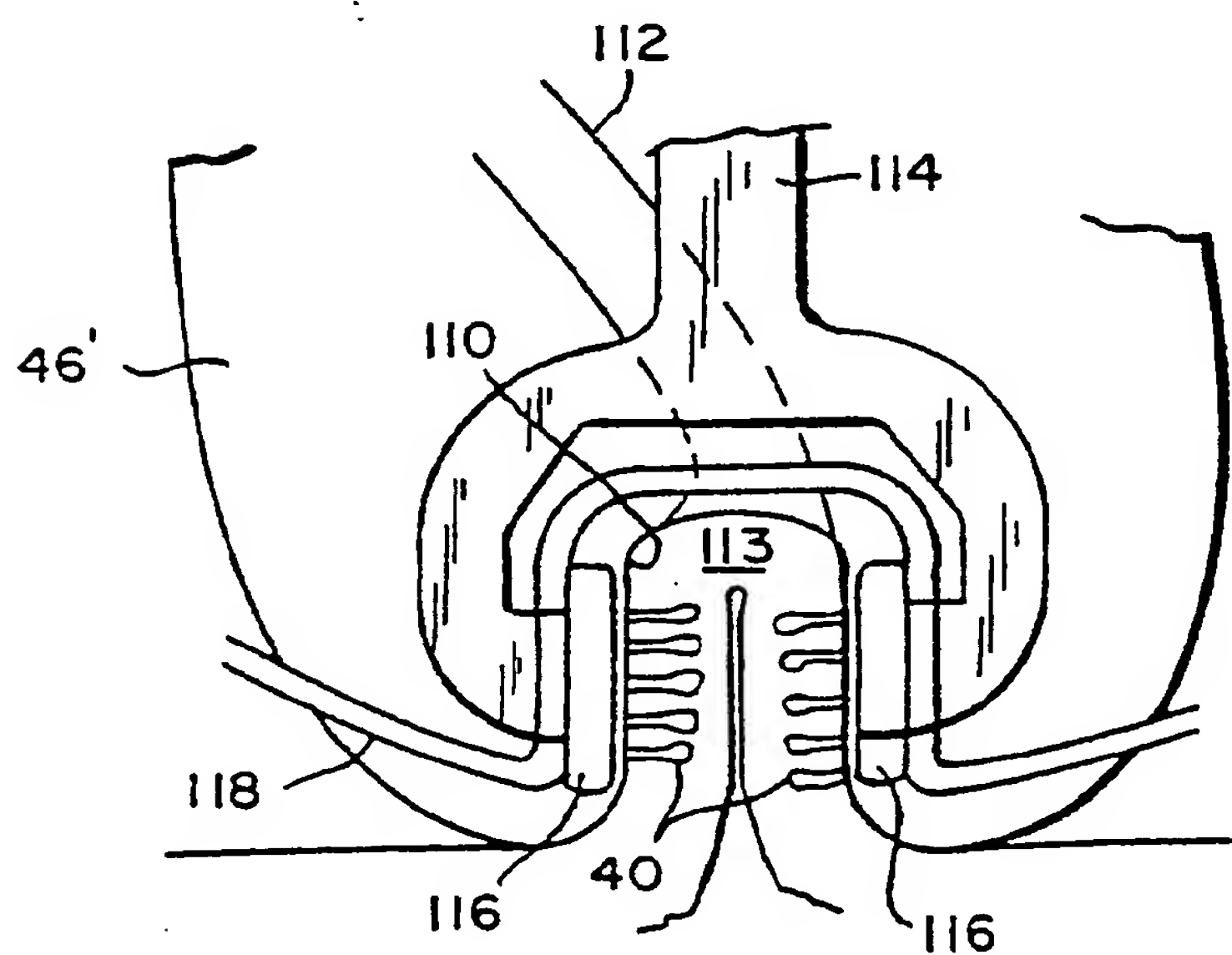


FIG. 10B



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 04 07 7257

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 5 059 192 A (ZAIAS NARDO) 22 October 1991 (1991-10-22) * column 3, line 23 - line 48 *	1,2,6,8, 17,29	A61B18/20
X	US 5 344 418 A (GHAFFARI SHAHRIAR) 6 September 1994 (1994-09-06) * column 4, line 47 - line 66; figure 7A *	3,4, 8-12,14, 18,21, 22,24	
X	US 5 282 797 A (CHESS CYRUS) 1 February 1994 (1994-02-01) * column 4, line 61 - column 5, line 66; figure 2 *	3-5,18, 23,24	
X	US 3 538 919 A (MEYER ROBERT G) 10 November 1970 (1970-11-10) * column 1, line 41 - column 2, line 2 *	1,2,13, 17,25, 26,28	
A	EP 0 142 671 A (BLOCK CAROL LTD) 29 May 1985 (1985-05-29) * claim 1 *	1,3,9, 11,18,24	TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61B
A	US 4 388 924 A (WEISSMAN HOWARD R ET AL) 21 June 1983 (1983-06-21) * abstract; figure 1 *	1,3,9, 11,18,24	
A	FR 2 591 902 A (COLLIN YVON) 26 June 1987 (1987-06-26) * page 6, line 2 - line 11 *	15,16, 19,20,28	
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The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 16 November 2004	Examiner Mayer-Martenson, E
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 04 07 7257

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	EP 0 565 331 A (ESC INC) 13 October 1993 (1993-10-13) * claim 4 *	1,3,9, 11,18,24	
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The present search report has been drawn up for all claims			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
Place of search The Hague		Date of completion of the search 16 November 2004	Examiner Mayer-Martenson, E
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

EPO FORM 1503 (3.92, (P04C01))



European Patent
Office

Application Number
EP 04 07 7257

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- ☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):
- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- ☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- ☒ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- ☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:



European Patent
Office

LACK OF UNITY OF INVENTION
SHEET B

Application Number
EP 04 07 7257

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1,2,6-8,10,14,15,16,17,29

laser for epilation with a wavelength of 680nm-1200nm

2. claims: 3-5,18-28

laser for epilation with cooled surface

3. claim: 9

laser for epilation with surface matching the refractive
index of skin

4. claims: 11-13

laser for epilation with element for converging optical
radiation

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 04 07 7257

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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(54)

Method for assessing pigmented skin

(57)

The present invention features a method of approximating the relative contribution of melanin and/or deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin.

Description**FIELD OF INVENTION**

5 [0001] The present invention relates to the assessment of pigmented skin.

BACKGROUND OF THE INVENTION

10 [0002] The chromatic characteristics of skin color arise from the interactions of light (primarily absorption and scattering) with the epidermis and the dermis. The primary light absorbers in skin are hemoglobin and melanin. Most of scattering is attributed to collagen fibers and in pigmented skin to melanosomes. Traditionally, skin redness is considered to arise due to locally elevated concentrations of hemoglobin, whereas skin pigmentation is attributed to melanin.

15 [0003] Human skin is structurally and optically heterogeneous. It consists of two discrete layers, the epidermis and the dermis, each with different biological structure and different optical properties arising from their individual absorbing and scattering constituents. The epidermis is a highly cellular tissue consisting of layers of keratinocytes. It is known that the primary absorber in the epidermis is melanin. It has also been shown (Kollias, et al., (1991) J Photochem Photobiol B 9(2): 135-160) that particulate melanin is a major contributor to epidermal scattering. Melanin is synthesized in specialized organelles, the melanosomes, which are manufactured in the melanocytes that are found at the basal layer of the epidermis. The melanosomes are secreted from the dendritic processes of the melanocytes, and they are
20 phagocytosed by the keratinocytes.

[0004] The dermis is essentially an acellular tissue sparsely populated by fibroblasts. It consists primarily of extra-cellular matrix components (collagen and elastin), blood vessels, and lymphatic vessels. Collagen microfibrils are organized into fibers and the fibers into bundles. These structures constitute the major cause of light scattering in the skin. Hemoglobin is found in the dermal blood supply and is responsible for the red appearance of skin, as in the case
25 of erythema. Skin hemoglobin is confined in networks of arterial and venous plexi that run approximately parallel to the skin surface and in small capillaries that run vertical to the skin surface and reach close to the dermal-epidermal junction in the form of capillary loops. Anatomically, one can distinguish a superficial arterial and venous plexus and a deeper plexus. The capillaries stem from the superficial arterial plexus and empty in the superficial venous plexus. The superficial and deeper plexi are interconnected through smaller vessels. At the deeper level, arteriovenous anastomoses (shunts) provide ways for blood flow to bypass superficial skin layers, thus enabling skin thermal regulation. Circulating erythrocytes in the blood vessels contain high concentrations of hemoglobin. The hemoglobin molecule has four heme groups, which can bind to and deliver oxygen molecules to the tissues. When these binding sites are unoccupied, the molecule is called deoxy-hemoglobin (deoxy-Hb) or reduced hemoglobin. When oxygen molecules occupy these binding sites, it is termed oxy-hemoglobin (oxy-Hb) or oxygenated hemoglobin. Each form of hemoglobin
35 has its own characteristic absorption profile (Kollias, (1995) Clin Dermatol 13(4):361-367).

[0005] It follows from the above that the visual perception of skin color is the cumulative result of contributions of various optically active molecules that are found in varying concentrations in the skin. The relative contributions of each chromophore can be evaluated quantitatively by analyzing the remittance spectra of skin tissue. Applicants have discovered that deoxy-hemoglobin not only contributes to erythema, but also surprisingly contributes to perceived
40 pigmentation of the skin. Applicants have accordingly modified the analysis of remittance spectra to take into account this discovery.

SUMMARY OF THE INVENTION

45 [0006] In one aspect, the present invention features a method of approximating the relative contribution of melanin responsible for the perceived pigmentation of an area of skin including the steps of (i) determining the absorbance of light at a wavelength of from about 620 nm to about 750 nm at such area of skin and (ii) subtracting the approximate relative contribution of deoxy-hemoglobin from such absorbance.

50 [0007] In another aspect, the present invention features A method of approximating the relative contribution of deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin including the steps of (i) determining the absorbance of light at a wavelength of from about 550 nm to about 590 nm at such area of skin and (ii) subtracting the approximate relative contribution of oxy-hemoglobin and melanin from such absorbance.

[0008] In another aspect, the present invention features a method of approximating the relative amount of melanin responsible for the perceived pigmentation of an area of skin, including the steps of: (i) measuring the reflectance of
55 a first light at a wavelength of from about 555 nm to about 565 nm, a second light at a wavelength of from about 570 nm to about 585 nm, a third light at a wavelength of from about 620 nm to about 650 nm, and a fourth light at a wavelength of from about 680 nm to about 750 nm at such area of skin; (ii) determining the first approximate relative contribution of melanin to such perceived pigmentation by determining the absorbance of the third light and the fourth

light at such area of skin; (iii) subtracting the first approximate relative contribution of melanin from the determined absorbance of the first light and the second light at such area of skin; (iv) determining the first approximate relative contribution of deoxy-hemoglobin from the recalculated absorbance of the first light and the second light of step (iii); and (v) subtracting the first approximate relative contribution of deoxy-hemoglobin from the first approximate relative contribution of melanin to obtain a final approximate relative contribution of melanin.

[0009] In another aspect, the present invention features a method of approximating the relative amount of deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin including the steps of: (i) measuring the reflectance of a first light at a wavelength of from about 555 nm to about 565 nm, a second light at a wavelength of from about 570 nm to about 585 nm, a third light at a wavelength of from about 620 nm to about 650 nm, and a fourth light at a wavelength of from about 680 nm to about 750 nm at such area of skin; (ii) determining the first approximate relative contribution of melanin to such perceived pigmentation by determining the absorbance of the third light and the fourth light at such area of skin; (iii) subtracting the first approximate relative contribution of melanin from the determined absorbance of the first light and the second light at such area of skin; and (iv) determining the first approximate relative contribution of deoxy-hemoglobin from the recalculated absorbance of the first light and the second light of step (iii).

[0010] In another aspect, the present invention features a method of approximating the relative contribution of melanin to a perceived pigmentation of an area of skin including the steps of: (i) examining such skin with a device including a light source and a reflectance detector, wherein the detector measures the reflectance from such area of skin of light generated by the light source of at a first wavelength of from about 555 nm to about 565 nm, at a second light wavelength of from about 570 nm to about 585 nm, at a third wavelength of from about 620 nm to about 650 nm, and at a fourth wavelength of from about 680 nm to about 750 nm at such area of skin; (ii) determining the first approximate relative contribution of melanin, to such perceived pigmentation by using the calculated absorbance of the third wavelength and the fourth wavelength at such area of skin; and (iii) further determining the approximate relative contribution of melanin by subtracting from the first approximate relative contribution of melanin the approximate relative contribution of deoxy-hemoglobin determined by the absorbance of the first wavelength and the second wavelength at such area of skin.

[0011] In another aspect, the present invention features a method of approximating the relative contribution of deoxy-hemoglobin to a perceived pigmentation of an area of skin including the steps of: (i) examining such area of skin with a device including a light source and a reflectance detector, wherein the detector measures the reflectance from such area of skin of light generated by the light source of at a first wavelength of from about 555 nm to about 565 nm, at a second light wavelength of from about 570 nm to about 585 nm, at a third wavelength of from about 620 nm to about 650 nm, and at a fourth wavelength of from about 680 nm to about 750 nm at such area of skin; (ii) determining the approximate relative contribution of melanin to such perceived pigmentation by using the calculated absorbance of the third wavelength and the fourth wavelength at such area of skin; and (iii) determining the approximate relative contribution of deoxy-hemoglobin by subtracting the first approximate relative contribution of melanin from the calculated absorbance value at the first wavelength and the second wavelength.

[0012] Other features and advantages of the present invention will be apparent from the detailed description of the invention and from the claims.

BRIEF DESCRIPTION OF FIGURES

[0013]

Fig 1a is a graph showing the change in concentration of oxy-hemoglobin at various SSR dosages.

Fig 1b is a graph showing the change in concentration of deoxy-hemoglobin at various SSR dosages.

Fig 1c is a graph showing the change in concentration of melanin at various SSR dosages.

Fig 2 is a graph showing the change in concentration of oxy-hemoglobin, deoxy-hemoglobin, melanin, and scattering at various applied pressures.

Fig 3 is a graph showing that perception of "skin pigmentation" depends on deoxy-hemoglobin concentration in a similar fashion to its dependence on melanin.

Fig 4 is graph showing the change in concentration of oxy-hemoglobin, deoxy-hemoglobin, melanin, and scattering following topical application of 3% H₂O₂

DETAILED DESCRIPTION OF THE INVENTION

[0014] It is believed that one skilled in the art can, based upon the description herein, utilize the present invention to its fullest extent. The following specific embodiments are to be construed as merely illustrative, and not limitative of the remainder of the disclosure in any way whatsoever.

[0015] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention belongs.

[0016] The present invention relates to a method of approximating the relative contribution of melanin and/or deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin. What is meant by the term "relative contribution" is either the (i) the concentration of the chromophore (e.g., melanin or deoxy-hemoglobin) at such area of skin or (ii) the percentage of the perceived pigmentation that is a result of the presence of such chromophore at the area of skin. Examples of pigmented areas of the skin include, but are not limited to, freckles, age spots, hyperpigmentation, dark circles, or tanned skin). The methods of the present invention utilize the absorbance of light at various wavelengths. What is meant by the phrase "a light at a wavelength" is radiation band centered at the specified wavelength wherein such band has a full width at half-maximum intensity of less than about 10 nm (e.g., for example less than about 5 nm).

[0017] The methods and devices of the present invention can be used to determine the source(s) of perceived pigmentation on areas of the skin. For example, if it is determined that the melanin contributes to the perceived pigmentation, skin lightening/depigmenting agents can be used to treat the area. Examples of such agents include, but are not limited to, ascorbic acid, kojic acid, and soy extracts. If it is determined that the deoxy-hemoglobin contributes to the perceived pigmentation, vasoactive agents can be used to treat the area. Examples of such agents include cortisone and hydrogen peroxide.

[0018] Objective quantitative evaluation of skin color using non-invasive instrumentation has been used since the early decades of the 20th century (Brunsting, L. A. and C. Sheard, (1929), *J Clin Invest* 7(4): 575-592). Since then spectrophotometers have become smaller and simpler in use. Many researchers have used methods based on reflectance measurements that either give "erythema" and "pigmentation" indices based on simple calculations (Diffey, et al., (1984) *Br J Dermatol* 111:663-672) or calculate tri-stimulus values ($L^*a^*b^*$ scale) that have been adopted by the international committee of standards (CIE) as the preferred method for color measurement (Westerhof, et al., (1986) *Photodermatol*, 3:310-314). In the latter method, L^* and b^* , as well as combinations of the two, have been used as "pigmentation" parameters, and a^* as the "erythema" parameter. Recent studies have showed that in both methods what is clinically perceived erythema and pigmentation does not correlate linearly with the calculated indices (Takiwaki, et al., (2002), *Skin Res Techn* 8:78-83 and Wagner et al., (2002), *Pigment Cell Res*, 15:5:379-384). A more accurate method is to analyze the remitted spectrum to its constituents based on Diffuse Reflectance Spectroscopy (DRS) (Kollias, et al., *Clin. Dermatol.* 13:36 (1995)). Apparent concentrations of melanin, oxy-Hb, and deoxy-Hb can be extracted from absorption spectra obtained by DRS, thus separating the vascular from the melanin reactions that are responsible for erythema and pigment. DRS measurements are rapid, non-invasive, objective, and quantitative. Instruments that perform DRS can be small, portable, and easy to use.

[0019] The absorbance curve was calculated as the logarithm of the ratio of the diffuse reflectance from a non-irradiated site to the diffuse reflectance from an irradiated site. In previous algorithms, pigment was evaluated from the absorbance curve as the slope of the fitted straight line over the wavelength range of 620-720 nm. Then, the absorbance curve was corrected for the pigment absorption and, finally, the oxy-Hb and deoxy-Hb absorption curves were fitted in the range of 550-580 nm, where they exhibit maxima. Such algorithms, however, over-estimate the contribution of melanin and under-estimate the contribution of hemoglobin to the perceived pigmentation.

[0020] It has been assumed that deoxy-hemoglobin contributes to the "red" color in skin just like oxy-hemoglobin, afterall, both of these chromophores appear red in vitro. Deoxy-hemoglobin in skin is found in the superficial venous plexus and in particular in the venules. These vessels are large enough (20-50 microns in diameter) so that light (in the yellow-green part of the spectrum) is almost completely attenuated when it tries to traverse through them. This means that they appear dark (almost black) and slightly reddish. Slight occlusion of blood flow or compression of venules causes an increase or a decrease in the amount of deoxy-hemoglobin resident in the venules and therefore a change in the color of the skin. A surprising result was that these changes in concentration of deoxy-hemoglobin in the skin appear like changes in melanin pigment.

[0021] The main reason why deoxy-hemoglobin contributes to a pigmented skin appearance is that the absorption spectrum of deoxy-hemoglobin in the 630-700 nm range is very similar to the absorption spectrum of epidermal melanin, so whatever light is transmitted has the color balance of pigment. Furthermore, the size of the vessels in the superficial venous plexus is such that the transmitted radiation through these vessels is approximately 50% lower than the incident intensity, and, therefore, they appear dark. Moreover, deoxy-hemoglobin is a dominant pigment in normal skin, contributing 30-50% to the perceived concentration of blood and equal in its contribution to that of oxy-hemoglobin and melanin to skin color.

Device for Reflectance Acquisition

[0022] In one embodiment, the reflectance acquisition can be accomplished by either point spectroscopy or multi-spectral imaging. In the case of point spectroscopy, the system can, in one embodiment, include a light source, a probe, and a reflectance detector. In one embodiment, the light source is a broad-band source that includes wavelengths from

about 560 to about 780 nm. Examples of such broadband sources include, but are not limited to, incandescent light sources, metal-halide light sources, halogen lamps, and broad-band light emitting diodes (LEDs). In one embodiment, the light source is a monochromatic or narrow band source (e.g., emitting a wavelength or wavelengths of light substantially within the range of from about 560 to about 780 nm). Examples of such light sources include, but are not limited to, tunable lasers, narrow-band LEDs, and filtered broad-band sources. A combination of two or more of the above light sources can also be used. Examples of the probes include, but are not limited to, a fiber optic bundle (e.g., for contact with the skin site of interest) or an integrating sphere (e.g., with an opening that comes in contact with the site of interest). In the case of an integrating sphere, care should be taken to account for the contribution of specular reflection to the total reflected signal. In the case where a broad-band light source is used, a dispersive element (such as a grating or a monochromator), or a filter (such as a narrow band interference filter or a liquid crystal tunable filter) should be used to filter the light prior to entering the detector (e.g., to filter the light prior to contact with the skin or to filter the reflected light off the skin prior to entering the detector). Examples of detectors include, but are not limited to, a single photodiode, a photodiode array, a CCD array, or a photomultiplier.

[0023] In the case of multispectral imaging (e.g., a series of images acquired at a selected few wavelengths of interest), the system can include a light source and an imaging detector. Examples of light sources include, but are not limited to, broadband or narrow band sources capable of illuminating the area of interest or a combination of light sources as discussed above. The detector can be a digital camera, such as a CCD or CMOS. In the case of broadband light source, the image needs to be filtered before reaching the detector to the appropriate wavelengths. In one embodiment, filtering can be accomplished by placing appropriate dispersive element or filter between the light source and the detector to filter the light entering the detector. In one embodiment for multispectral imaging, orthogonal polarization between the illumination and the detector is used in order to eliminate specular reflection (e.g., glare). Orthogonal polarization can be accomplished by placing a linear polarizer in front of the light source and a second linear polarizer in front of the detector (e.g., the camera). The second linear polarizer can be placed in such a way that its polarization plane is orthogonal to the polarization plane of the first linear polarizer.

Algorithm for Analysis of Absorbance

[0024] Applicants have discovered a new corrected algorithm for the analysis of reflectance spectra from skin that separates the approximate vascular from the approximate melanin contributions to the perceived erythema and/or pigmentation by taking into account the spectral contribution of deoxy-Hb in the red region of the spectrum (620-700 nm). In one embodiment, the procedure is as follows: (a) the diffuse reflectance spectrum from skin is referenced to uninvolved normal skin of the same individual, (b) the spectrum is fitted with a straight line in wavelength ($f(\lambda)$) in the spectral range 620-720 nm (the slope of the straight line is believed to be related to the concentration of melanin in the skin); (c) the straight line that best fits the data is then subtracted from the whole spectrum, which results in a spectrum that is identical with the baseline at wavelengths in the range 620-720 nm and deviating from baseline to shorter wavelengths; (d) the difference spectrum is fitted using the absorption parameters of oxy-hemoglobin and deoxy-hemoglobin at the wavelengths of 560 and 578 nm, which is accomplished by solving a system of two equations and two unknowns, the result is an apparent concentration of oxy-hemoglobin and of deoxy-hemoglobin; (e) the concentration of deoxy-hemoglobin is used to calculate the contribution of this chromophore to the measured slope of the fitted line of step (b); (f) the apparent concentration of melanin is related to the slope of the line of step (b) corrected for the absorption of deoxy-hemoglobin in this wavelength range given by step (e); (g) an apparent scattering parameter can be calculated from the value of the corrected fitted line of step (f) at an arbitrary selected wavelength in the range of 630 - 820 nm; (h) the corrected fitted line of step (f) is subtracted from the whole spectrum (similarly to step (c)), and (i) the new difference spectrum is fitted using the absorption parameters of oxy-hemoglobin and deoxy-hemoglobin at the wavelengths of 560 and 578 nm (similarly to step (d)), which is accomplished by solving a system of two equations and two unknowns, the result is the corrected apparent concentration of oxy- and of deoxy-hemoglobin.

[0025] In one embodiment of the algorithm, the above steps can be condensed to the following equations:

[0026] The intercept (int_o) and the slope (m_o) of the absorbance spectra in the 620 - 720 nm range can be calculated from the values of the spectrum at the wavelengths 620 nm and 720 nm (S^{620} and S^{720} correspondingly):

$$int_o = \frac{720 \times S^{620} - 620 \times S^{720}}{720 - 620}, \quad m_o = \frac{S^{720} - S^{620}}{720 - 620} \quad (1)$$

[0027] The absorbance values at 560 and 578 nm corrected for melanin (initial approximation) are given by:

$$S_c^{560} = S^{560} - (m_o \times 560 + \text{int}_o), \quad S_c^{578} = S^{578} - (m_o \times 578 + \text{int}_o) \quad (2)$$

[0028] The concentrations of oxy-Hb ($[\text{HbO}_2]$) and deoxy-Hb ($[\text{Hb}]$) can be calculated from these corrected values of the absorption spectrum and the extinction coefficients of oxy-Hb and deoxy-Hb at 560 nm and 578 nm, $\alpha_{\text{HbO}_2}^{560}$, $\alpha_{\text{HbO}_2}^{578}$, α_{Hb}^{560} , and α_{Hb}^{578} :

$$[\text{HbO}_2] = \frac{\alpha_{\text{Hb}}^{560} \times S_c^{578} - \alpha_{\text{Hb}}^{578} \times S_c^{560}}{\alpha_{\text{Hb}}^{560} \times \alpha_{\text{HbO}_2}^{578} - \alpha_{\text{Hb}}^{578} \times \alpha_{\text{HbO}_2}^{560}}, \quad [\text{Hb}] = \frac{\alpha_{\text{HbO}_2}^{578} \times S_c^{560} - \alpha_{\text{HbO}_2}^{560} \times S_c^{578}}{\alpha_{\text{Hb}}^{560} \times \alpha_{\text{HbO}_2}^{578} - \alpha_{\text{Hb}}^{578} \times \alpha_{\text{HbO}_2}^{560}} \quad (3)$$

The approximate relative contribution of oxy-hemoglobin and deoxy-hemoglobin can be used to examine vascular components of the skin and its related skin conditions, such as erythema, acne, inflammation, rosacea, and spider veins.

[0029] Finally, the corrected melanin concentration can be calculated given the slope of the deoxy-Hb extinction coefficient in the range 620-720 nm, $Sl_{\text{Hb}}^{620-720}$:

$$[\text{melanin}] = m_o - [\text{Hb}] \times Sl_{\text{Hb}}^{620-720} \quad (4)$$

The corrected values for oxy-Hb and deoxy-Hb concentrations can be calculated from equations (2) and (3) after substituting m_o with the corrected melanin concentration given in equation (4).

[0030] The approximate relative contribution of the light scattering can be calculated from:

$$sc = m_o \times \lambda_{sc} + \text{int}_o \quad (5)$$

where λ_{sc} is the chosen wavelength in the range 630-820nm. The approximate relative contribution of scattering can be used to examine dermal collagen and its related skin conditions, such as wrinkles and fine lines.

[0031] The above algorithm can be applied to point spectroscopy as well as to hyper- or multi- spectral imaging. Hyper-spectral imaging refers to a series of images acquired at different wavelengths, in such a way that a spectrum can be reconstructed for each individual pixel of the image based on the intensity values of the particular pixel throughout the wavelength range of acquisition. Multi-spectral imaging refers to a series of images acquired at a selected few wavelengths of interest.

[0032] Before any analysis of the hyper- or multi-spectral images takes place, care should be taken that the spectral images are registered to cancel any motion artifacts that may have occurred during image acquisition. In one embodiment, image registration includes image translation and rotation, but not image dilation, as the latter may compromise the quantitative nature of the algorithm.

[0033] In the case of hyper-spectral imaging, the plot of the intensity value of a pixel versus the acquisition wavelength is equivalent to a reflectance spectrum (scaled from 0 to 255 for 8 bit images) of the imaged object at the spatial position of the pixel. The following procedure describes, in one embodiment, how to convert the hyper-spectral spectrum of a pixel to an absorbance spectrum: (a) the percent reflectance spectrum is calculated by taking the ratio of the pixel intensity values to either the maximum allowed intensity (255 for 8 bit images), the reflectance from a white standard, or an image from a wavelength from about 800 to about 900 nm; (b) the estimated specular reflectance is subtracted from the ratio of step (a) (specular reflectance is given by the Fresnel law and for human skin this value is approximately 0.04); and (c) the negative logarithm of the corrected ratio of step (b) plotted against the acquisition wavelengths is the resulting absorbance spectrum.

[0034] Once the absorbance spectrum has been calculated, the procedure described above can be used to evaluate the chromophore values at each pixel. After normalization (byte scaling), the values of each chromophore for all pixels can be displayed as separate images, also referred to as "chromophore maps." See, e.g., Stamatas et al., (2003) Proc. SPIE 4959:77-82 for chromophore maps calculated by a previous algorithm.

[0035] In one embodiment, a similar "curve-fitting" procedure can be used to calculate apparent values of other chromophores native to human skin or externally applied. Some examples of native pigments not mentioned above include, but are not limited to, methemoglobin (absorbance at 404 nm and 635 nm), bilirubin (absorbance at 460 nm), beta-carotene, and water (absorbance bands at 970 nm, 1100 nm, etc.). Externally applied chromophores include, but

are not limited to, materials that absorb in UV, visible, or NIR, such as sunscreens, cosmetic formulations, make-up, lipstick, and topical drugs. Thus, a similar approach can be used to quantify deposition of an ingredient of a topical formulation.

[0036] Alternatively to hyper-spectral imaging a small number of acquisition wavelengths can be selected that would result in chromophore maps using the above procedure. This approach is termed multi-spectral imaging. The requirements for selecting the right acquisition wavelengths are as follows: (a) One image is required to be acquired in the wavelength region of the deoxy-hemoglobin maximum at 560 nm and has to have a bandwidth of less than 5 nm at each side, in order to avoid the maxima of oxy-hemoglobin at 555 nm and 578 nm; (b) One image is required to be acquired in the wavelength region of the beta band of oxy-hemoglobin (at 578 nm) and has to have a bandwidth of less than 10 nm at each side; and (c) At least two images are required to be acquired in the wavelength region of 620 nm - 720 nm with the wavelengths being chosen as far from each other as possible to cover evenly the region.

[0037] Melanin and scattering values can be calculated from the (c) images as described in the procedure above and oxy- and deoxy-hemoglobin values from a 2x2 system using the intensities of images (a) and (b). To calculate values for the four chromophores mentioned here, a minimum of four images at different wavelengths should be used.

Clinical Studies

[0038] Twelve healthy individuals with skin photo-types III-IV participated in the study. The source of irradiation was a 500W UVC-filtered Xenon arc solar simulator (Solar Light Co., Philadelphia, PA). The instrument was calibrated right before its use, and the total power of the source was recorded every 3 to 4 hours throughout the day to assure its stability and spectral quality following Colipa (The European Cosmetic, Toiletry, and Perfumery Association) guidelines. Initially the minimum solar simulator radiation (SSR) dose to induce perceptible erythema (MED) was determined on the back of each participant. Clinical erythema was evaluated 24 hours after the irradiation. Following MED determination, each individual was irradiated on the back with SSR doses of 0.7, 1.0, 1.5, 2.1, and 3 MED. The skin reactions were evaluated on days 1, 7, 14, and 21 after exposure. Evaluations included cross-polarized photography, DRS measurements, and clinical assessment of erythema and pigmentation by an experienced dermatologist.

[0039] In a second experiment, a pressure cuff was applied to the upper arm of ten healthy volunteers. The applied pressure was set at levels of 0, 20, 30, 40, and 60 mmHg. Measurements were taken 5 min after each pressure level was set to allow for the vasculature to equilibrate. Changes in skin color due to vascular reactions were evaluated visually with a chromameter and with a DRS instrument.

[0040] In a third experiment, 2 inch diameter cotton pads soaked in 3% H₂O₂ (U.S.P. topical anti-infective) in aqueous solution were applied on the volar forearm of ten healthy volunteers for 1 min. The pads were removed and the skin area was dried with fresh cotton pads. DRS measurements and visible evaluation of the treated sites were performed at 0, 5, 10, 15, and 20 min after removal of the pads.

Diffuse Reflectance Spectroscopy (DRS)

[0041] The DRS instrument contained a quartz halogen light source (Ocean Optics, Boca Raton, FL), a bifurcated fiber bundle (Multimode Fiber Optics, East Hanover, NJ), an S2000 spectrometer (Ocean Optics, Boca Raton, FL), and a laptop computer (Toshiba Tecra, Irvine, CA). One leg of the fiber bundle was connected to the light source and the other to the spectrometer. Measurements were performed by placing the common end of the fiber bundle gently in contact with skin so as not to perturb the blood content. A reflectance spectrum was acquired in the range of 400-820 nm. Apparent concentrations of hemoglobin and melanin were calculated from the diffuse reflectance spectra. See, e.g., Kollias et al., Photodermatol 5:53-60 (1988). Briefly, the absorbance curve was calculated as the logarithm of the ratio of the diffuse reflectance from a non-irradiated site to the diffuse reflectance from an irradiated site. Pigment was evaluated from the absorbance curve as the slope of the fitted straight line over the wavelength range of 620-720 nm. Then, the curve was corrected for the pigment absorption, and finally, the oxy-Hb and deoxy-Hb absorption curves were fitted in the range of 550-580 nm, where they exhibit maxima, as set forth in Table 1.

Table I

Chromophore	Absorption curve characteristic
Melanin	Monotonic increase towards short wavelengths; Approximates linear in the region 600 - 750 nm
Oxy-Hemoglobin	Maxima at 415, 540, and 577 nm
Deoxy-Hemoglobin	Maxima at 430 and 555 nm

[0042] The reproducibility of the method for calculating apparent hemoglobin concentrations was calculated as the error between measurements, and it was found to be better than 10%. It needs to be noted that for the collection geometry used here, an underestimation of the reflectance at the long wavelengths (red/NIR region) compared to the shorter wavelengths (blue/green region) is anticipated. However, the measurements were always performed relative to baseline, or to neighboring untreated skin, and, therefore, such artifacts have been normalized.

Data Analysis

[0043] Linear regressions of the data were calculated using the least square errors algorithm. The goodness of fit is given by the correlation coefficient (R-squared). Statistical significance was calculated using the Student's t-test for paired data distributions.

UV Irradiation Experiment

[0044] UV-induced erythema was typically evaluated on day 1 after irradiation, while pigmentation was evaluated on day 7. The time course of changes in the concentration of oxy-Hb, deoxy-Hb, and melanin are shown in Figs 1a, 1b, and 1c. On day 1, after irradiation the observed skin reaction was classified as clinical "erythema". The visual observation of erythema correlated well with a dramatic increase in oxy-Hb and deoxy-Hb, as calculated from the spectroscopic data (Figs. 1a and 1b). The observed skin reaction on day 7 was classified clinically as "pigmentation", which correlated with an increase in melanin (Fig. 1c). However, the levels of both hemoglobins were significant on day 7, indicating that there is a strong vascular contribution to the observed reaction (Figs. 1a and 1b). On day 14, the reaction was again classified as "pigmentation", and although the melanin levels remained elevated, the concentration of deoxy-Hb was still above baseline (Fig. 1b). On day 21, the observed pigmentation was almost exclusively due to melanin (Fig. 1c). Although deoxy-Hb is still measurably above baseline, its contribution at 0.1 level was not visibly perceptible.

Pressure cuff experiment

[0045] In the pressure cuff experiment, increasing pressure resulted in a reduction of the values of L^* and b^* as measured by the chromameter corresponding to darker and less yellow color respectively. On the contrary, the value of a^* increased corresponding to a more red appearance. Although the color changes were recorded with the chromameter, it is of interest to note that visually the change in skin color was hard to observe. The reason was that the human eye works better in contrast and since the pressure was applied on the whole of the arm, the color change was uniform and, therefore, difficult to detect. DRS analysis showed that the only chromophore that was affected by changing the applied pressure was deoxy-Hb, which increased linearly with pressure (Fig. 2). Oxy-Hb and melanin remained practically unaltered. The characteristic angle, $\alpha = \arctan((L^*-50)/b^*)$, is a measure of the perceived pigmentation in such a way that when apparent pigmentation increases this parameter decreases. See, e.g., Park, et al., Clinexp Dermatol 24:315-320 (1999). In the present experiment, the characteristic angle decreased with increasing pressure in all volunteers, indicating that pressure-induced increases in blood stasis can be perceived as increased pigmentation (Fig. 3).

Hydrogen Peroxide Experiment

[0046] Application of cotton pads soaked in 3% hydrogen peroxide for 1 min induced a decrease in perceptible skin pigmentation that lasted for 10-15 min after removal of the pads. Analysis of DRS spectra showed that deoxy-Hb significantly decreased during the period of blanching (Fig. 4). Oxy-Hb decreased slightly, but within instrument variability (determined to be ± 0.1 oxy-Hb units). Melanin and dermal scattering remained unchanged at baseline levels.

[0047] It is understood that while the invention has been described in conjunction with the detailed description thereof, that the foregoing description is intended to illustrate, and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the claims.

Claims

1. A method of approximating the relative contribution of melanin responsible for the perceived pigmentation of an area of skin, said method comprising the steps of (i) determining the absorbance of light at a wavelength of from 620 nm to 750 nm at said area of skin and (ii) subtracting the approximate relative contribution of deoxy-hemoglobin from said absorbance.

2. A method of claim 1, wherein said method comprises determining said absorbance of light at least two different wavelengths, wherein said wavelengths are from 620 nm to 750 nm.
- 5 3. A method of claim 1 or claim 2, wherein the approximate relative contribution of deoxy-hemoglobin is determined by determining the absorbance of light at a wavelength from 550 nm to 590 nm at said area of skin.
- 10 4. A method of approximating the relative contribution of deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin, said method comprising the steps of (i) determining the absorbance of light at a wavelength of from 550 nm to 590 nm at said area of skin and (ii) subtracting the approximate relative contribution of oxy-hemoglobin and melanin from said absorbance.
- 15 5. A method of claim 4, wherein said method comprises determining said absorbance of light at least two different wavelengths, wherein said wavelengths are from 550 nm to 590 nm.
- 20 6. A method of claim 4 or claim 5, wherein the approximate relative contribution of melanin is determined by determining the absorbance of light at a wavelength from 620 nm to 750 nm at said area of skin.
- 25 7. A method of approximating the relative amount of melanin responsible for the perceived pigmentation of an area of skin, said method comprising the steps of:
 - (i) measuring the reflectance of a first light at a wavelength of from 555 nm to 565 nm, a second light at a wavelength of from 570 nm to 585 nm, a third light at a wavelength of from 620 nm to 650 nm, and a fourth light at a wavelength of from 680 nm to 750 nm at said area of skin;
 - (ii) determining the first approximate relative contribution of melanin to such perceived pigmentation by determining the absorbance of said third light and said fourth light at said area of skin;
 - (iii) subtracting said first approximate relative contribution of melanin from the determined absorbance of said first light and said second light at said area of skin;
 - (iv) determining the first approximate relative contribution of deoxy-hemoglobin from the recalculated absorbance of said first light and said second light of step (iii); and
 - 30 (v) subtracting the first approximate relative contribution of deoxy-hemoglobin from said first approximate relative contribution of melanin to obtain a final approximate relative contribution of melanin.
- 35 8. A method of approximating the relative amount of deoxy-hemoglobin responsible for the perceived pigmentation of an area of skin, said method comprising the steps of:
 - (i) measuring the reflectance of a first light at a wavelength of from 555 nm to 565 nm, a second light at a wavelength of from 570 nm to 585 nm, a third light at a wavelength of from 620 nm to 650 nm, and a fourth light at a wavelength of from 680 nm to 750 nm at said area of skin;
 - (ii) determining the first approximate relative contribution of melanin to such perceived pigmentation by determining the absorbance of said third light and said fourth light at said area of skin;
 - 40 (iii) subtracting said first approximate relative contribution of melanin from the determined absorbance of said first light and said second light at said area of skin; and
 - (iv) determining the first approximate relative contribution of deoxy-hemoglobin from the recalculated absorbance of said first light and said second light of step (iii).
- 45 9. A method of approximating the relative contribution of melanin to a perceived pigmentation of an area of skin, said method comprising the steps of:
 - (i) examining said area of skin with a device comprising a light source and a reflectance detector, wherein said detector measures the reflectance from said area of skin of light generated by said light source of at a first wavelength of from 555 nm to 565 nm, at a second light wavelength of from 570 nm to 585 nm, at a third wavelength of from 620 nm to 650 nm, and at a fourth wavelength of from 680 nm to 750 nm at said area of skin,
 - (ii) determining the first approximate relative contribution of melanin to such perceived pigmentation by using the calculated absorbance of said third wavelength and said fourth wavelength at said area of skin; and
 - 50 (iii) further determining the approximate relative contribution of melanin by subtracting from said first approximate relative contribution of melanin the approximate relative contribution of deoxy-hemoglobin determined by the absorbance of said first wavelength and said second wavelength at said area of skin.

10. A method of approximating the relative contribution of deoxy-hemoglobin to a perceived pigmentation of an area of skin, said method comprising the steps of:

- (i) examining said area of skin with a device comprising a light source and a reflectance detector, wherein said detector measures the reflectance from said area of skin of light generated by said light source of at a first wavelength of from 555 nm to 565 nm, at a second light wavelength of from 570 nm to 585 nm, at a third wavelength of from 620 nm to 650 nm, and at a fourth wavelength of from 680 nm to 750 nm at said area of skin;
- (ii) determining the approximate relative contribution of melanin to such perceived pigmentation by using the calculated absorbance of said third wavelength and said fourth wavelength at said area of skin; and
- (iii) determining the approximate relative contribution of deoxy-hemoglobin by subtracting said first approximate relative contribution of melanin from the calculated absorbance value at said first wavelength and said second wavelength.

11. A method of any one of claims 7 to 10, wherein said device comprises a filter device such that the light emitted from said light source is filtered to said first wavelength, said second wavelength, said third wavelength, and said fourth wavelength, optionally prior to measurement by said reflectance detector.

12. A method of any one of claims 7 to 11, wherein said reflectance detector is a spectrometer.

13. A method of any one of claims 7 to 11, wherein said reflectance detector is a camera.

14. A method of claim 13, wherein said method is conducted at a plurality of areas of the skin where the absorbances at such areas of skin are determined from the pixels obtained by said camera.

15. A method of claim 14, wherein said relative contribution of melanin or deoxy-hemoglobin at said areas of skin is represented as an image of such areas of skin.

FIG. 1a

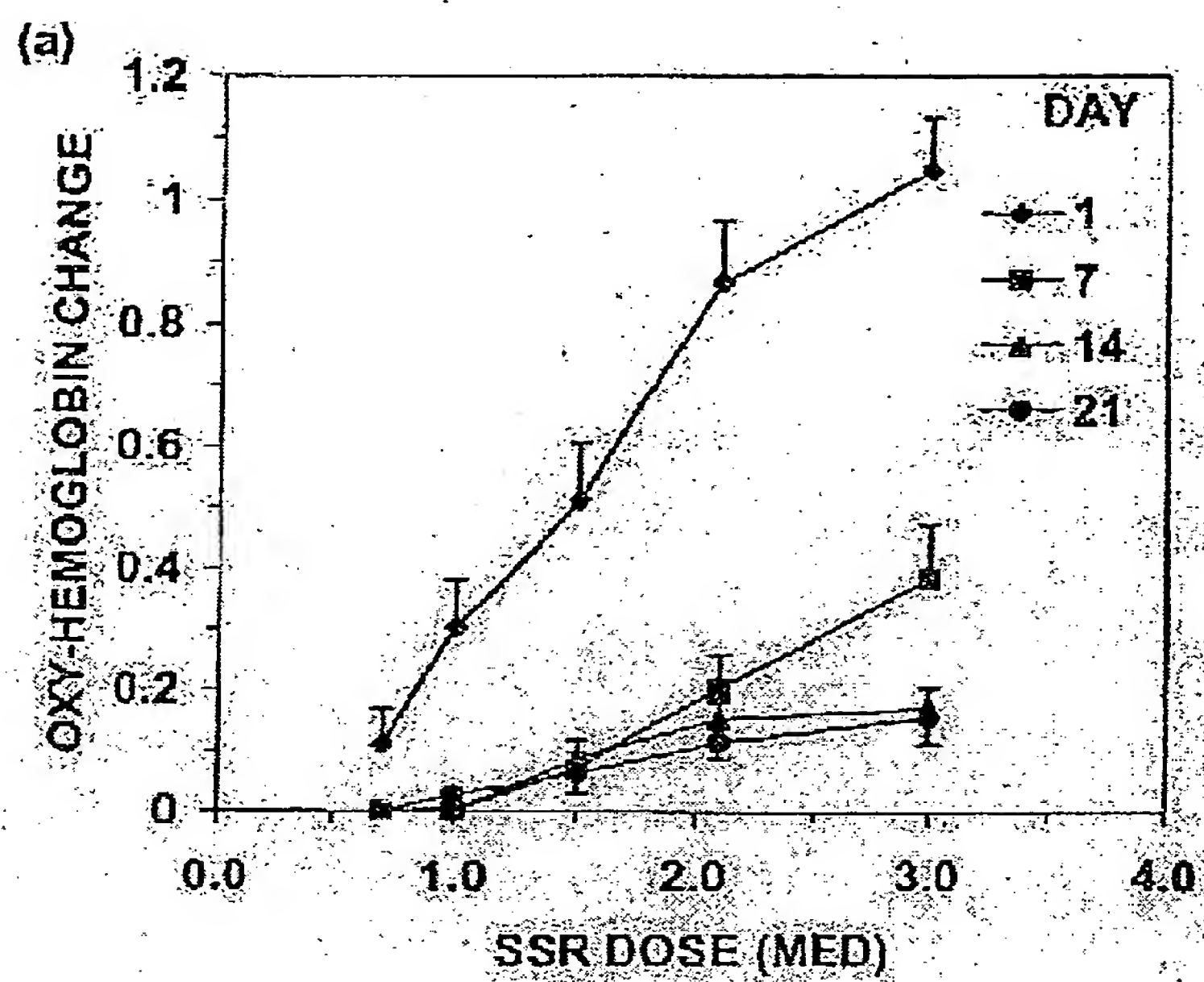


FIG. 1b

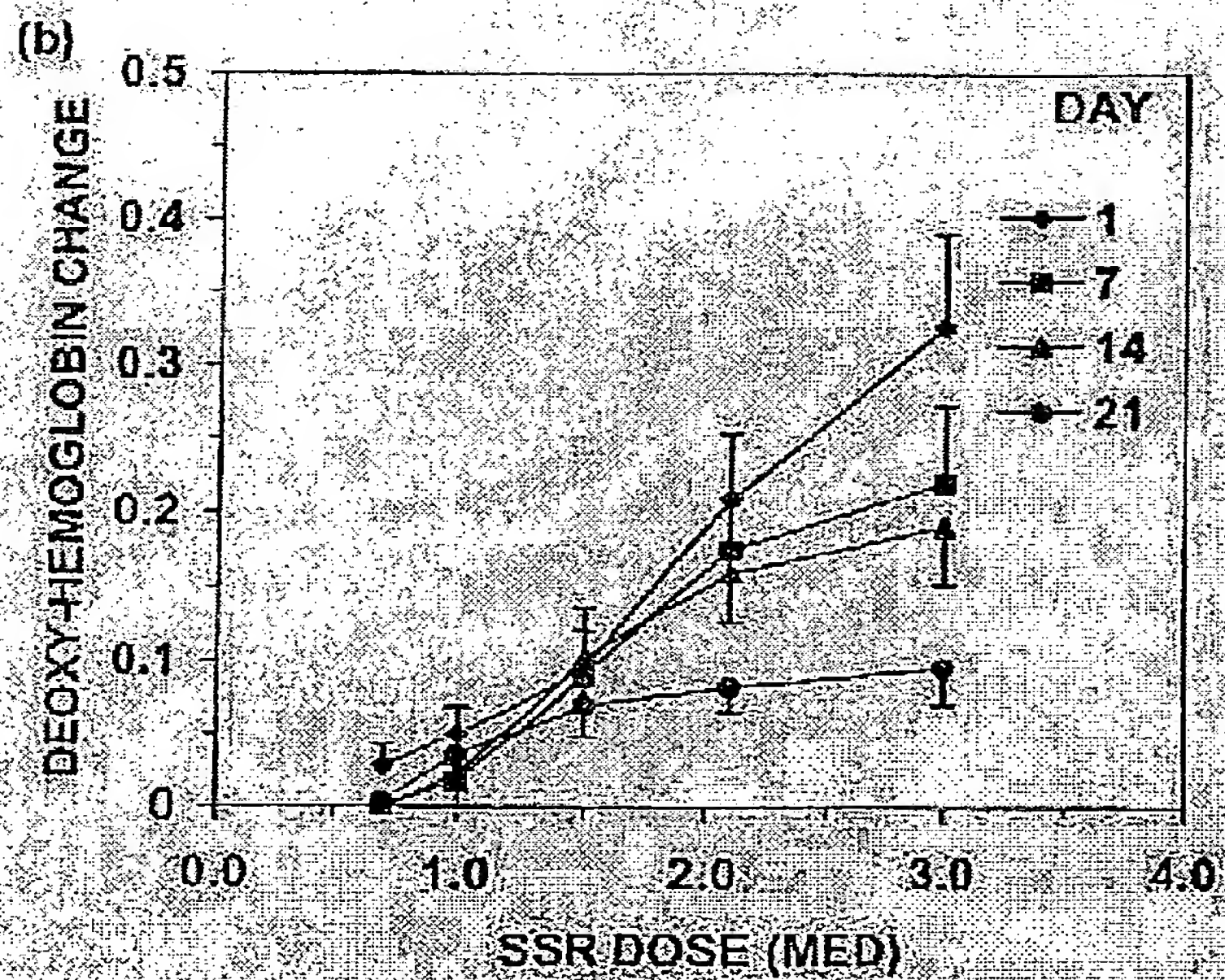


FIG. 1c

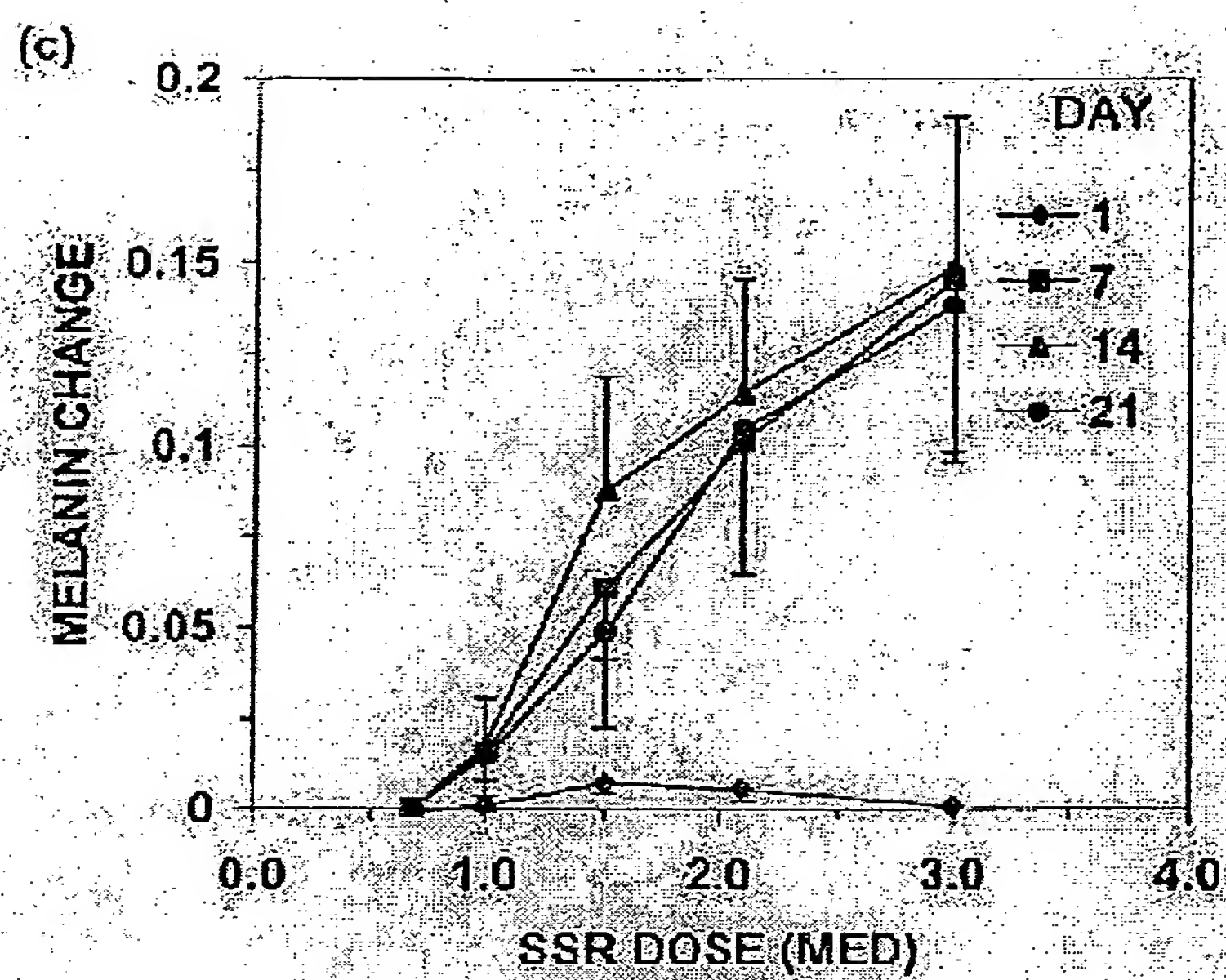


FIG. 2

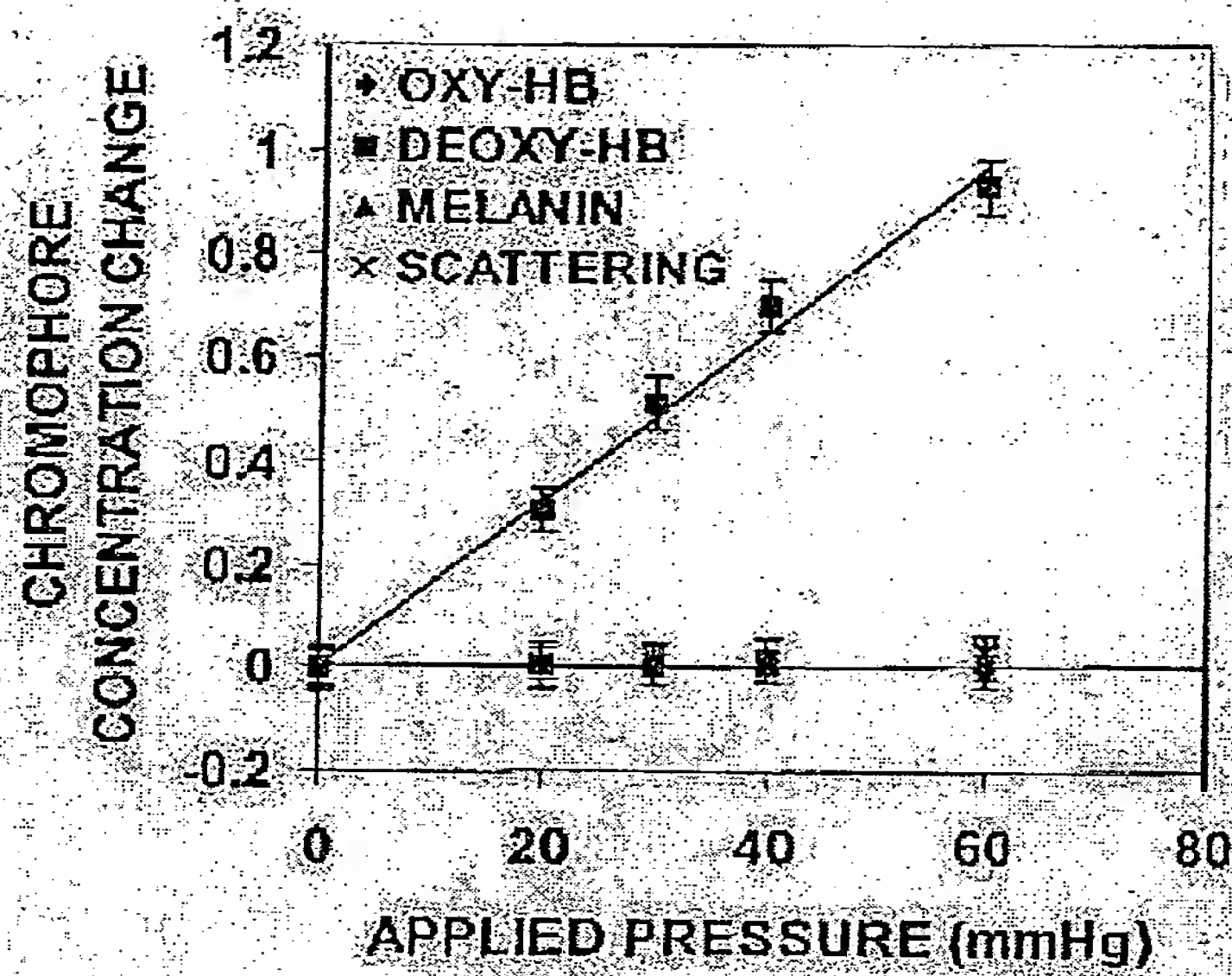


FIG. 3

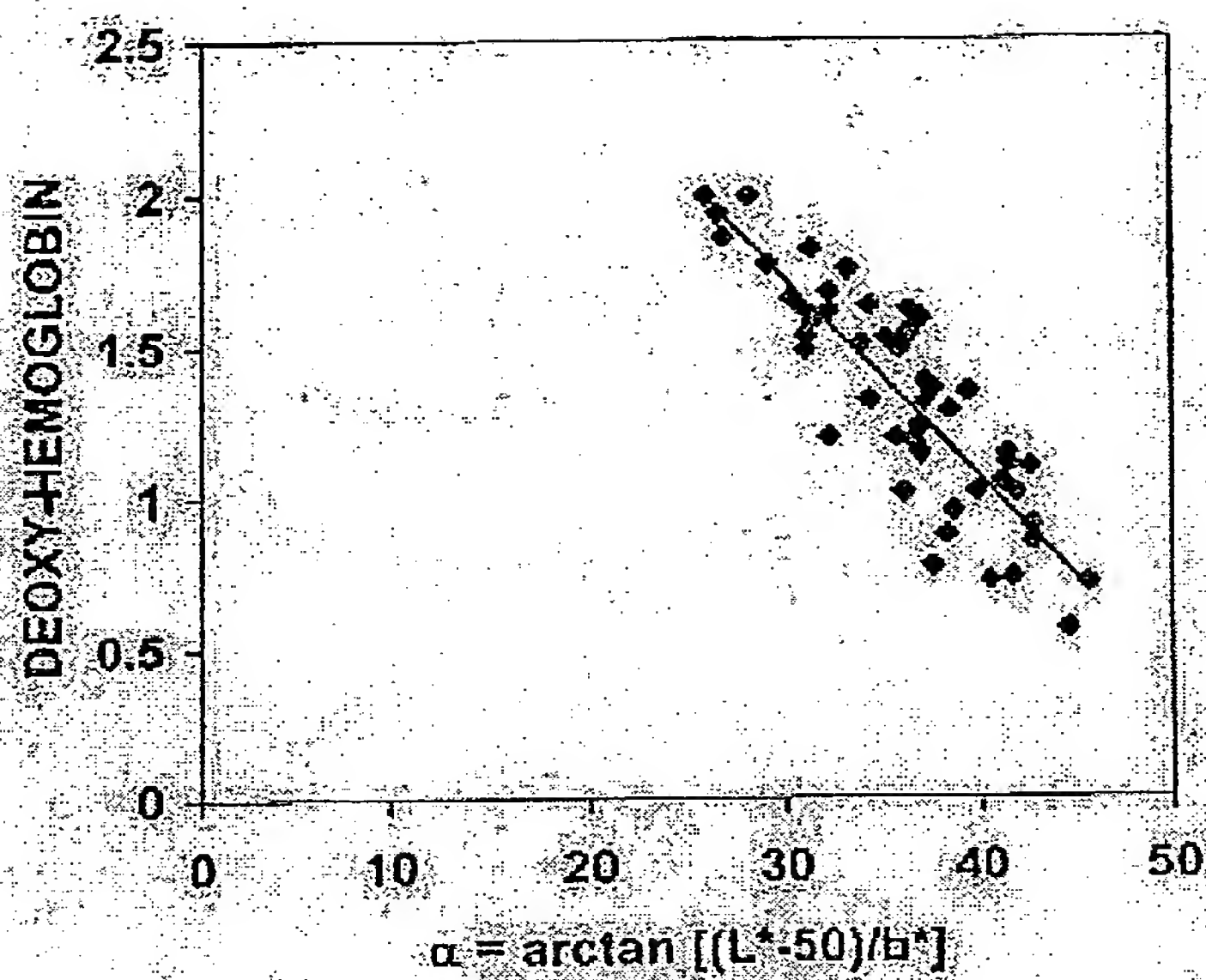
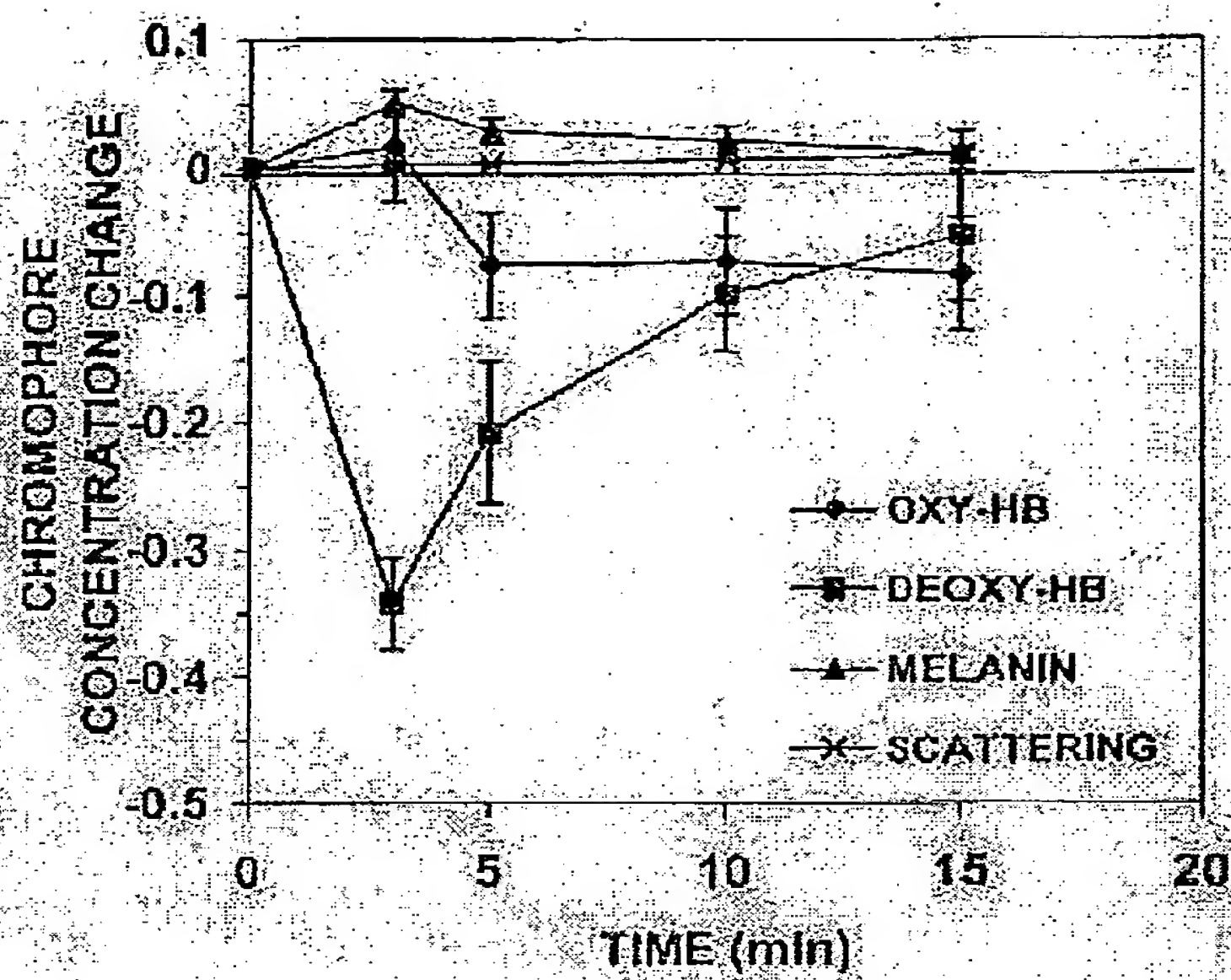


FIG. 4





European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 04 25 5139

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The present search report has been drawn up for all claims			
Place of search Munich		Date of completion of the search 29 October 2004	Examiner Willig, H
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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EPO FORM 1503 03 B2 (P04G01)



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<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document</p>			

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EP 04 25 5139

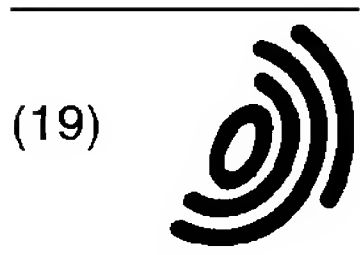
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(54) Light irradiation unit for diagnosing and treating skin problems

(57) A light irradiation unit (1), of the type that comprises a control processor (4) and a handpiece (2), which is connected electrically to the processor (4) and is provided with a light source and with at least one filter that is interposed between the source and a front opening of the handpiece (2) for the exit of the light. The handpiece (2) is enclosed by two symmetric half-shells (2a,

2b), which are mutually coupled so as to constitute a chamber, and the light source and the filter are fitted on a cartridge (7) that can be inserted in a portion of the chamber; the cartridge (7) is associable within the portion by way of locking means. A plate made of a material that is permeable to light radiation is fitted on the cartridge (7) proximate to the filter and parallel thereto.

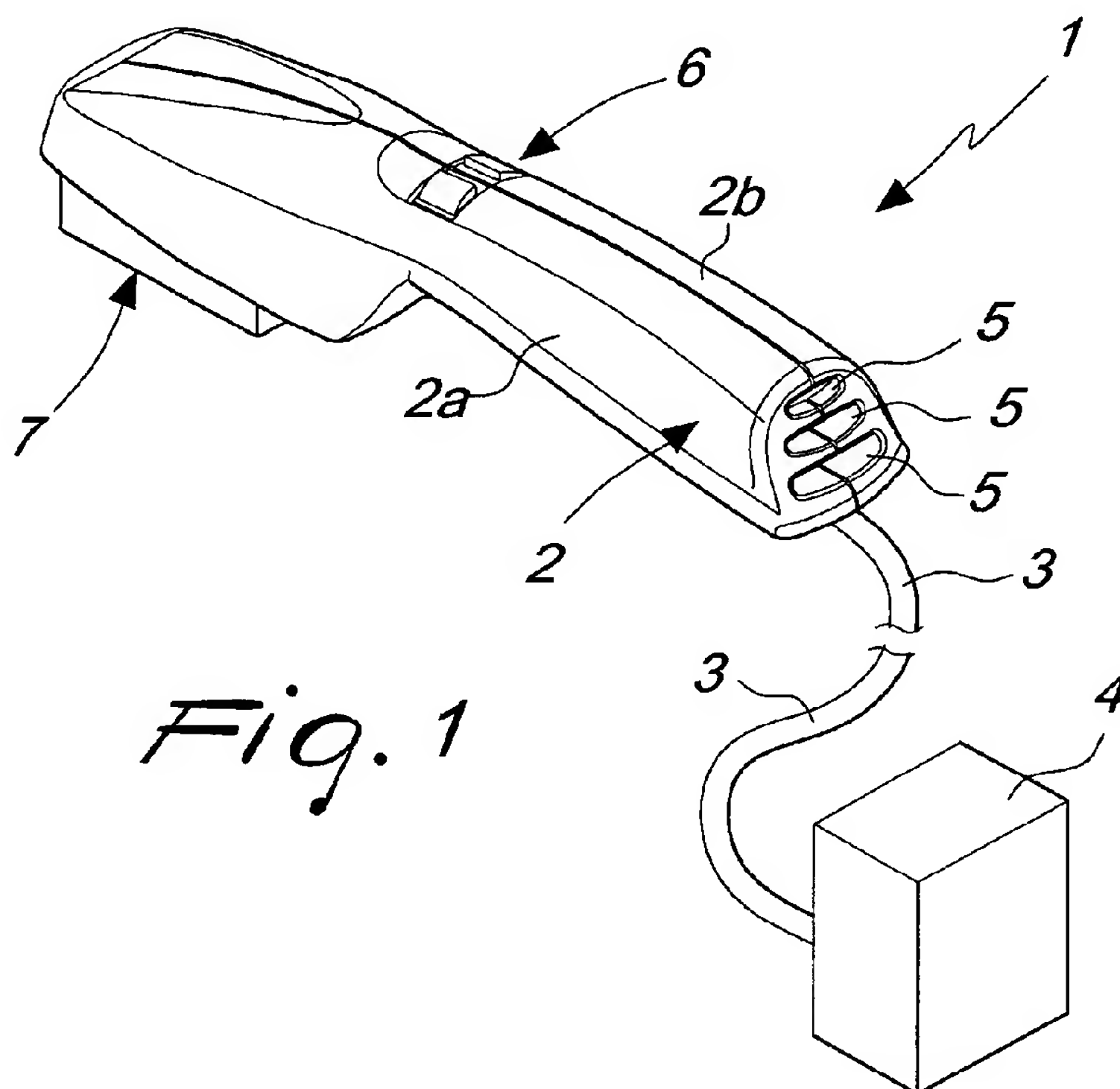


Fig. 1

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Description

[0001] The present invention relates to a light irradiation unit for diagnosing and treating skin problems and for hair removal treatments.

[0002] By subjecting the skin to light beams of various intensities and various duration, it is possible to obtain from said skin information regarding its state and characteristics, which can be used for diagnostic purposes.

[0003] Further, different combinations of light irradiation of the skin can facilitate the reduction of some kinds of dermatological disorder and improve their aesthetic appearance. For example, with treatments of this kind it is possible to eliminate or reduce the number of fine capillary vessels (telangiectasias) and to provide permanent or semipermanent hair removal on the treated surfaces.

[0004] Devices are commercially available which are provided with a lamp commonly used for flashing luminous indicators (for example sirens with flashing lamp for flying-squad vehicles), which has a higher power because it has not only a visual effect but also a heat generation effect.

[0005] The lamp is fitted inside a mirror-finished parabolic reflector, which causes the light to converge toward a specific point on the skin. All this is inserted within a handpiece provided with a button for activating the emission of light radiation.

[0006] The lamp emits radiation with a very broad wavelength range, from the ultraviolet to the infrared; accordingly, a filter that allows only the radiation of the intended wavelength to pass is installed and interposed between the lamp and the skin.

[0007] During operation, the lamp emits heat and accordingly gets hot and also heats the skin excessively.

[0008] In currently commercially available devices, the handpiece in which the lamp is mounted is cooled by means of a suction circuit; the skin of the patient is located proximate to the filter that shields the light source and is therefore struck by an intense flow of heat.

[0009] It should be noted that the filter can be touched both intentionally (for example by inserting a finger in the front opening from which the light flashes exit) and unintentionally (for example by treating a curved skin portion and pressing the handpiece excessively against said skin, one runs the risk of contact between the skin and the surface of the filter).

[0010] Contact with the filter (which can reach high temperatures) certainly entails skin burns: therefore, this apparatus must be used with great skill and cannot be left unattended in the presence of the patient (especially after use, when the filter is still hot and burns are possible if it is handled incorrectly).

[0011] The lamp and the filter constitute an assembly by means of which it is possible to treat only some aesthetic problems: it is convenient to associate various filters with a same type of light source or to vary both the source and the filter to obtain a series of assemblies suit-

able for all kinds of skin and for all kinds of treatment.

[0012] Currently, the entire handpiece is replaced by adopting the one that is most suited for the type of skin and the type of treatment: this entails the purchase of a certain number of handpieces, which however are very expensive and bulky.

[0013] There are constructive solutions which use interchangeable lamp-filter assemblies: rapid replaceability allows far easier use, but over time it can entail wear of the parts that slide with respect to each other during replacement, rendering the coupling of the assembly to the handpiece scarcely stable.

[0014] The aim of the present invention is to obviate the cited drawbacks and meet the mentioned requirements, by providing a light irradiation unit in which contact with the filter is not possible and in which it is possible to ensure rapid replacement and anchoring of the filter and the lamp.

[0015] Within this aim, an object of the present invention is to provide a unit in which localized cooling of the handpiece is provided in order to keep at a low temperature all the parts that make contact with the operator and the patient.

[0016] Another object of the present invention is to provide a unit that is simple, relatively easy to provide in practice, safe in use, effective in operation, and has a relatively low cost.

[0017] This aim and these and other objects that will become better apparent hereinafter are achieved by the present light irradiation unit, of the type that comprises a control processor and a handpiece, which is connected electrically to said processor and is provided with a light source and with at least one filter that is interposed between said source and a front opening of said handpiece for the exit of the light, characterized in that said handpiece is enclosed by two symmetric half-shells, which are mutually coupled so as to constitute a chamber, in that said light source and said filter are fitted on a cartridge that can be inserted in a portion of said chamber, said cartridge being associable within said portion by way of locking means, and in that a plate of a material that is permeable to light radiation is fitted on said cartridge proximate to said filter and parallel thereto.

[0018] Further characteristics and advantages of the present invention will become better apparent from the following detailed description of a preferred but not exclusive embodiment of a light irradiation unit, illustrated by way of non-limiting example in the accompanying drawings, wherein:

Figure 1 is a top perspective view of a handpiece of a unit according to the invention;

Figure 2 is a partially sectional bottom perspective view of a handpiece of a unit according to the invention;

Figure 3 is a bottom perspective view of a handpiece during the extraction of a cartridge of a unit according to the invention;

Figure 4 is a sectional front view of a handpiece of a unit according to the invention, in which the half-shells are spaced;

Figure 5 is a sectional front view of a handpiece of a unit according to the invention, in which the half-shells are closed together;

Figure 6 is a top rear perspective view of a handpiece of a unit according to the invention, in which the half-shells are spaced;

Figure 7 is a bottom front perspective view of a handpiece of a unit according to the invention, in which the half-shells are closed together;

Figure 8 is a sectional rear view of a unit according to the invention, in which the half-shells are closed together;

Figure 9 is a perspective view of a lamp of a unit according to the invention;

Figure 10 is a plan view of a parabolic reflector of a unit according to the invention;

Figure 11 is a front top perspective view of a cartridge of a unit according to the invention;

Figure 12 is a bottom rear perspective view of a cartridge of a unit according to the invention.

[0019] With reference to the figures, the reference numeral 1 generally designates a light irradiation unit.

[0020] The unit 1 is constituted by a handpiece 2, which is connected by means of a multicore cable 3 to a control processor 4.

[0021] The handpiece 2 has an elongated shape, with smooth and radiused surfaces; at the rear, above the hole for the insertion of the cable 3, there are through slots 5. The actuation buttons 6 are provided in an upper region, at the central portion of the handpiece 2.

[0022] Each handpiece 2 is constituted by two half-shells 2a and 2b, which are mutually coupled by means of at least one screw 2c, which passes through the half-shell 2a and engages within an appropriately provided seat of the half-shell 2b.

[0023] A cartridge 7 is accommodated in the front part of the handpiece 2 and is provided with a plurality of front openings 8 and with at least one rear slot 8a (the openings 8 and the slot 8a allow the circulation of air within the cartridge 7). The cartridge 7 has the appearance of a block, with a flat bottom 9 made of a material that is not transparent to light radiation. Plates 7a are applied to the cartridge 7 and are constituted by a flat mask 10 provided with an opening 11. The cartridge 7 has, in an upper region, a transparent screen, the filter 12, which has a rectangular area with sides that measure respectively 50 and 30 mm; the filter 12 can be made of materials such as glass, quartz and sapphire but also of other plastic or ceramic materials or of other kinds of material having particular filtering actions with respect to light radiation. Beyond the filter 12, also above the cartridge 7, there is a phototype detector 13.

[0024] In the rear part of the cartridge 7 there are pins 14 for connection to the handpiece 2, which are suitable

to be coupled electrically to the connection socket 14a of the handpiece 2.

[0025] The cartridge 7 is constituted by a parabolic reflector 15. Inside the parabolic reflector 15 there is a receptacle 16 for a lamp 17, which is shaped like two parallel and mutually proximate cylinders which are radiused at two ends and end, at their opposite ends, with respective electrical contacts 18. The patient can be subjected to light radiation having a wavelength comprised between 1 and 2000 nanometers.

[0026] A cooling fan 19 is installed longitudinally inside the handpiece 2 in the rear part: when the fan 19 is active, it aspirates air through the holes 5 and conveys it through a duct (delimited between the bottom 9 of the cartridge 7 and the region that surrounds the lamp 17) toward a front opening constituted by the slots 8.

[0027] The entire cartridge 7 is detachable and can be replaced with other cartridges 7 that have different filters 12, suitable for performing different therapies. For removal, it is necessary to resort to the use of a wrench C, which engages in the head of the screw 2c: by loosening the screw 2c, the two half-shells 2a and 2b are moved mutually apart and the cartridge 7 is disengaged from the clamping action, allowing its extraction; the new cartridge 7, once arranged within the half-shells 2a and 2b so that the pins 14 engage in the connection socket 14a, is fastened between the half-shells 2a and 2b, preventing its movement, by re-tightening the screw 2c with the wrench C. A plate 7a is accommodated and superimposed above the cartridge 7, is made at least partially of a material that is permeable to light radiation, and is designed to prevent direct contact of the skin of the patient with the surface of the filter 12. The surface of the filter 12, although being separate from the lamp 17, is heated considerably by said lamp, and this makes it potentially dangerous for the skin of the patient. The presence of the plate 7a, which in turn is separated from the filter 12 by means of an air gap (through which the air is conveyed forcibly by means of the fan 19), provides assurance of the patient against the risk of burns. The plate 7a is flat and is provided with two perimetric bands 7b, which are arranged at right angles thereto and are provided with end protrusions 7c for anchoring to the side walls of the cartridge 7; the cartridge 7 has, along its side walls, proximate to the open surface, from which the filter 12 can be accessed, a pair of longitudinal grooves 7d, which are suitable to accommodate stably the protrusions 7c.

[0028] The phototype detector 13 is a very important accessory, which is used to detect the type of skin being treated at a given moment. There are various kinds of skin, according to a scale defined by Fitzpatrick; this scale defines the reaction of the skin subjected to the emission of light, such as for example sunlight. This classification defines six types of skin: a first type, which always burns; a second type, which burns occasionally; a third type, which burns and occasionally tans; a fourth type, which tans and occasionally burns; a fifth type,

which tans; and a sixth type, which tans and does not burn.

[0029] The phototype detector 13 allows to diagnose the patient's phototype, so as to subject the patient to the most suitable therapy.

[0030] The phototype detector 13 is arranged near the lamp 18, but can also be arranged in other parts or separately from the cartridge 7.

[0031] A temperature sensor is inserted in the cartridge 7 and is connected to the processor 4 for controlling and lighting the lamp 17; this allows to check that the lamp 17 does not exceed a certain temperature that might damage the assembly 7 and/or burn the skin of the patient being treated. The temperature sensor can be electronic, electric, electromechanical or of any type that has these functions.

[0032] Each cartridge 7 differs according to the type of filter 12 fitted therein; in order to recognize it, the assembly 7 is provided with an electronic recognition apparatus.

[0033] Since the filter 12 is a non-detachable part of the block 7, the problem of recognizing the filter 12 is reduced to the problem of recognizing the electric circuit of the block 7 on which it is installed.

[0034] The operation of the invention is as follows: once the therapy to which the patient is to be subjected is known, the type of assembly 7 suitable for said therapy is chosen and is inserted in the handpiece 2 by sliding the bottom 9 into the appropriately provided receptacle and by making the pins 14 mate with the socket 14a; the filter detector 12 indicates on a display the type of filter that is installed.

[0035] By pressing one of the buttons 6 arranged on the top of the handpiece 2, the phototype detector 13 is activated and identifies the characteristics of the skin of the patient, checking the reflection on the skin of the light radiation, emitted by a light source, by means of a photodiode. The result of the test is indicated on the display.

[0036] Depending on the characteristics of the skin of the patient, the operator selects the most suitable program and starts the treatment, keeping the handpiece 2 orientated so that the lamp 17 faces the portion of skin to be treated.

[0037] The temperature of the lamp 17 is monitored constantly by the temperature sensor, which sends a signal that is proportional to the temperature of the lamp 17 to the processor 4, which adjusts the duration and frequency of the flashes in succession to avoid overheating. If a temperature limit is reached, the processor 4 disables the operation of the lamp 17.

[0038] During operation, the cooling fan 19 operates and keeps the temperature of the lamp 17 low.

[0039] The simultaneous presence of cooling means that act locally (fan 19) and of a plate 7a that separates the skin of the patient from the high-temperature surfaces makes the handpiece very simple to use and protects the patient, avoiding the risk of burns.

[0040] The possibility to replace the cartridges 7

makes it easier for operators to perform the treatment; moreover, the need to fasten the inserted cartridge 7 each time gives the advantage of always achieving the correct insertion of the cartridge 7 in the handpiece 2, making sure that it cannot detach accidentally and fall (and thus certainly be damaged) or provide a poor contact between the pins 14 and the socket 14a, with consequent possible malfunction and damage of the circuits.

[0041] It has thus been shown that the invention achieves the intended aim and objects.

[0042] The invention thus conceived is susceptible of numerous modifications and variations, all of which are within the scope of the inventive concept.

[0043] For example, it is possible to block the cartridge 7 by way of other fastening means. By using a toggle lever that is articulated to a half-shell 2a and engages in a protrusion of the other half-shell 2b, it would be possible to block the cartridge 7 firmly, both due to the mutual fastening of the half-shells 2a and 2b and due to the interference between the toggle lever and the cartridge 7.

[0044] Other equally valid embodiments may provide for the presence of grub screws (or regular screws) that are rigidly coupled to the surface of the half-shells 2a and 2b and engage, by screwing, respective receptacles formed in the side walls of each cartridge 7.

[0045] All the details may further be replaced with other technically equivalent ones.

[0046] In the embodiments described, individual characteristics, given in relation to specific examples, may actually be interchanged with other different characteristics that exist in other embodiments.

[0047] Moreover, it is noted that anything found to be already known during the patenting process is understood not to be claimed and to be the subject of a disclaimer.

[0048] In practice, the materials used, as well as the shapes and dimensions, may be any according to requirements without thereby abandoning the scope of the protection of the appended claims.

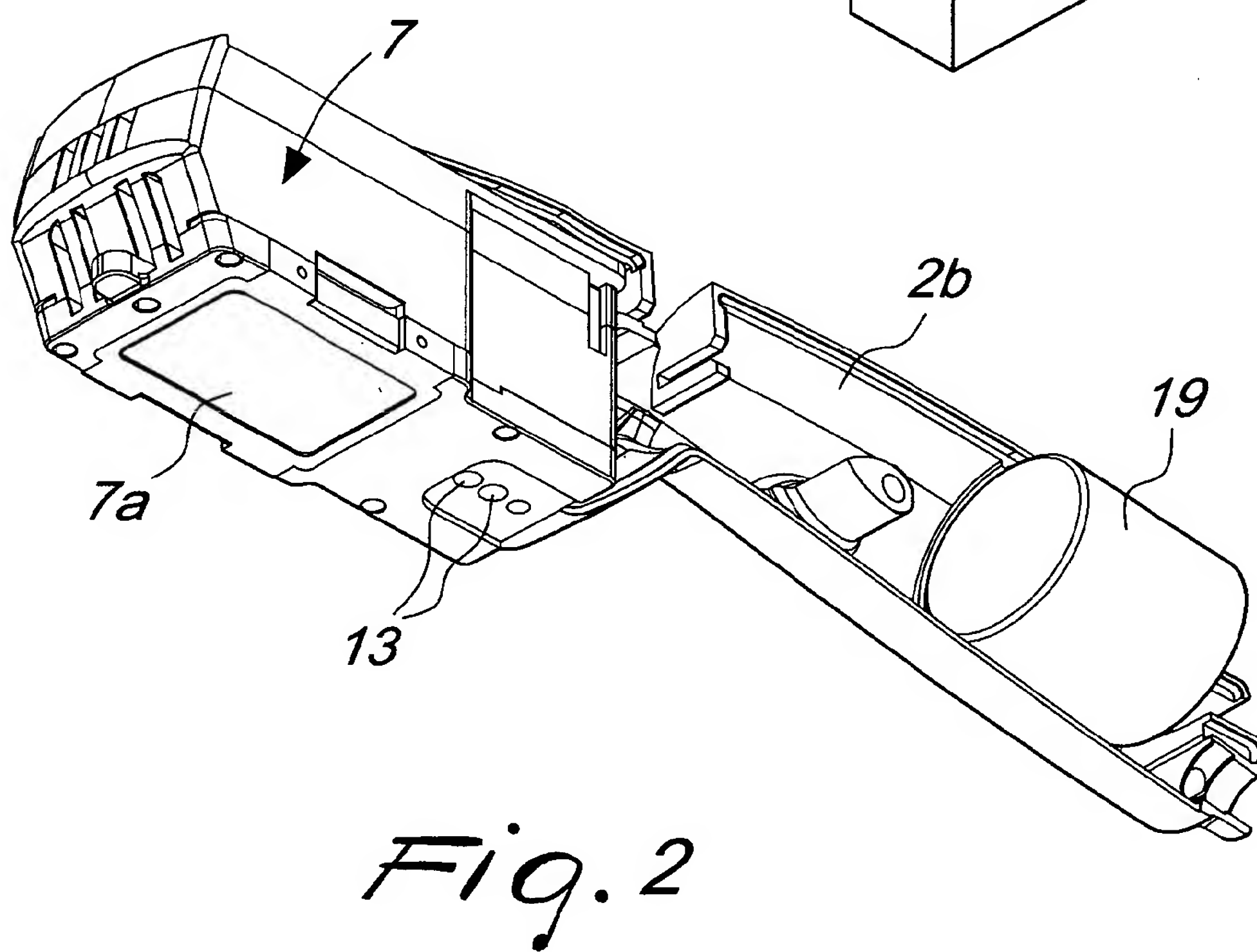
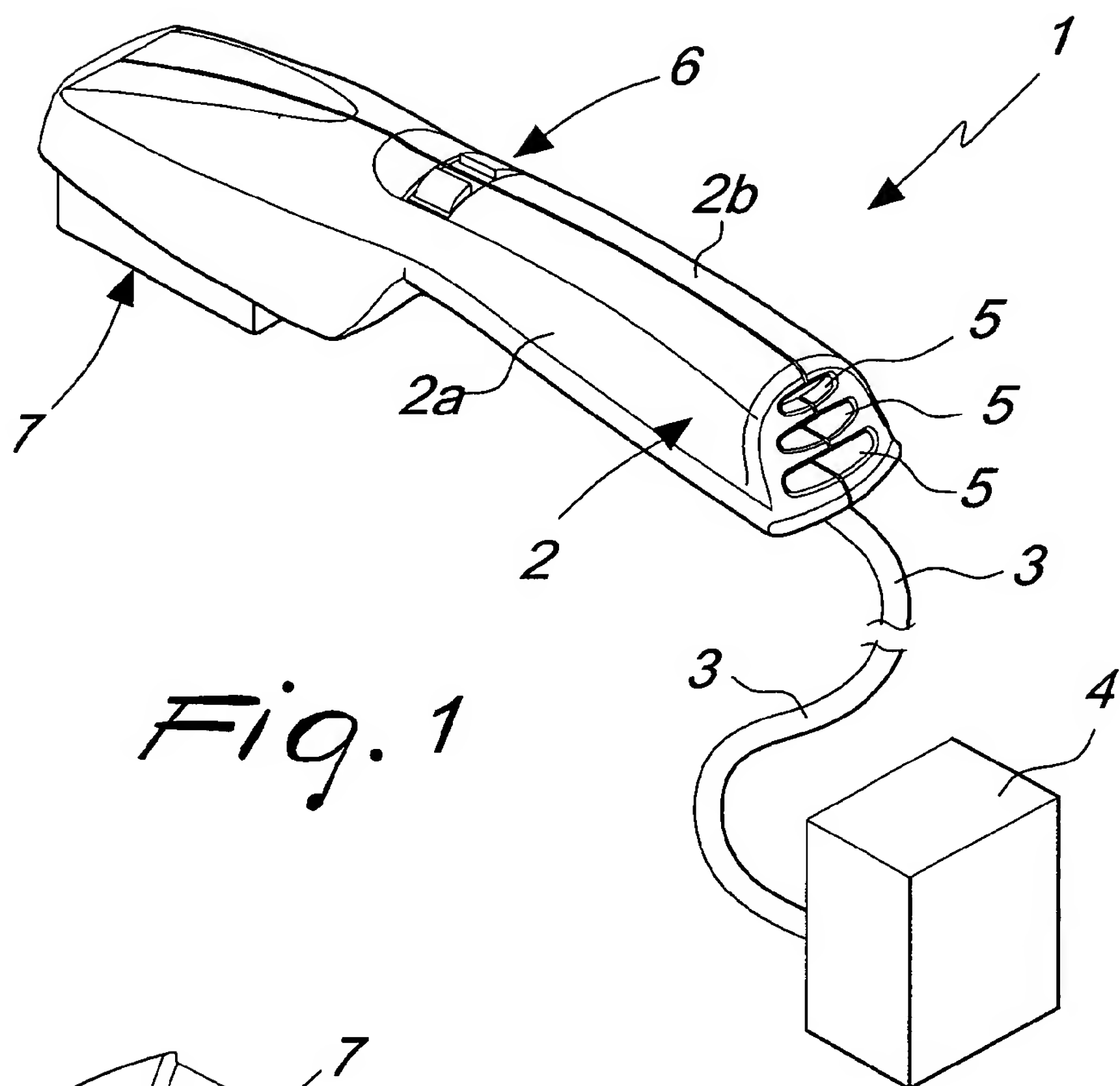
[0049] The disclosures in Italian Patent Application No. BO2003A000717 from which this application claims priority are incorporated herein by reference.

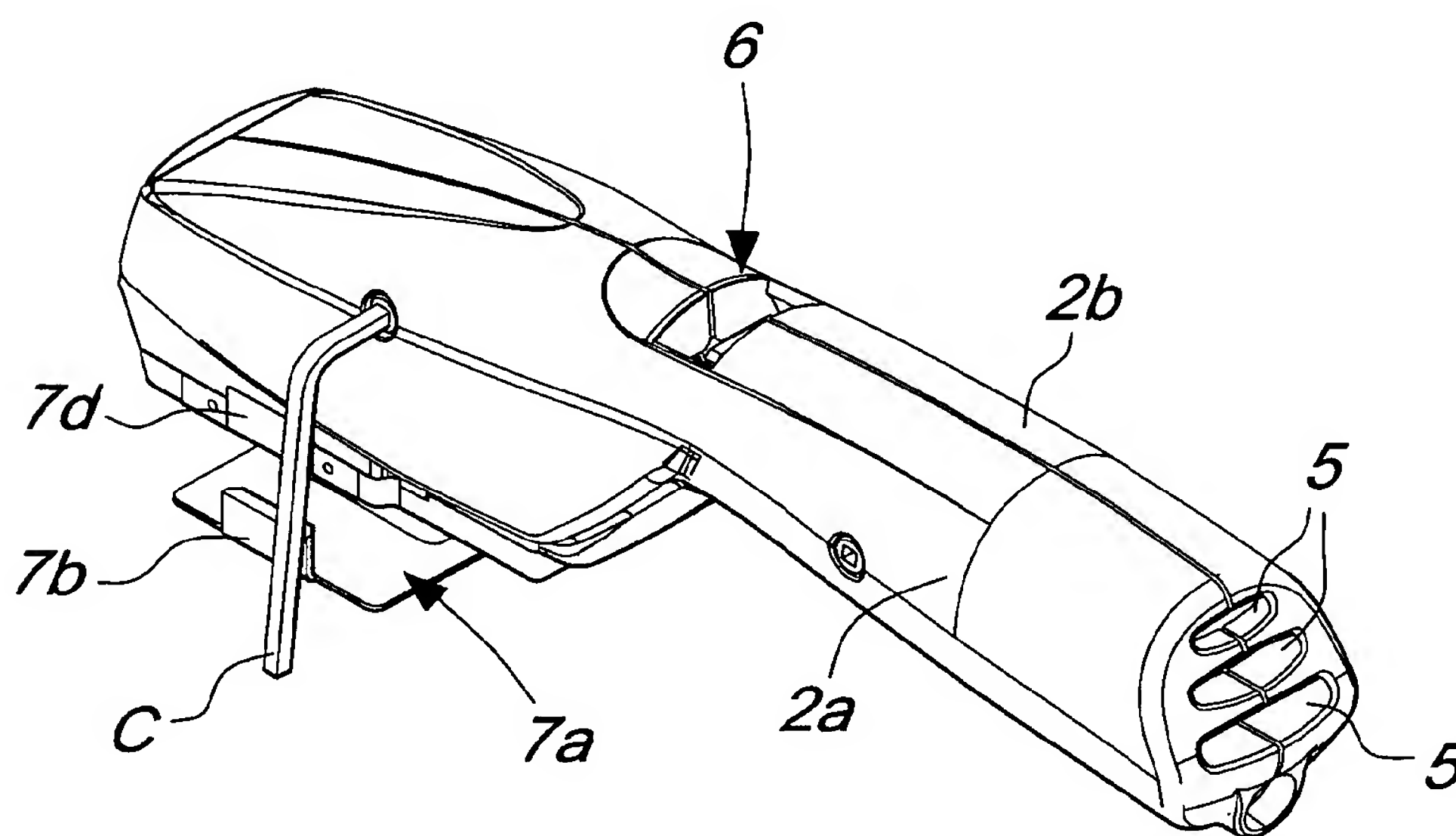
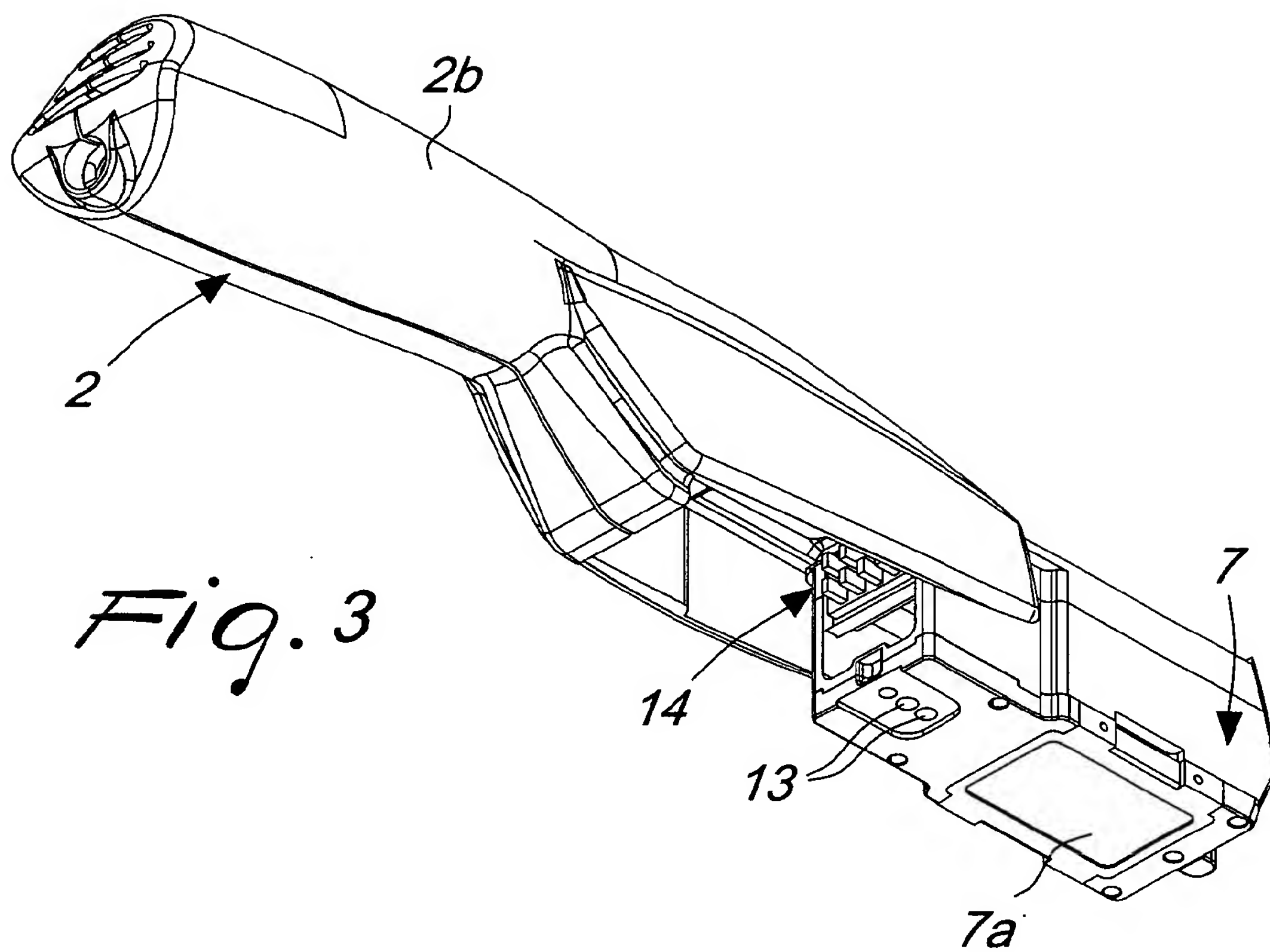
[0050] Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly such reference signs do not have any limiting effect on the interpretation of each element identified by way of example by such reference signs.

Claims

1. A light irradiation unit, of the type that comprises a control processor (4) and a handpiece (2), which is connected electrically to said processor (4) and is

- provided with a light source (17) and with at least one filter (12) that is interposed between said source (17) and a front opening of said handpiece (2) for the exit of the light, **characterized in that** said handpiece (2) is enclosed by two symmetric half-shells (2a, 2b), which are mutually coupled so as to constitute a chamber, **in that** said light source (17) and said filter (12) are fitted on a cartridge (7) that can be inserted in a portion of said chamber, said cartridge (7) being associable within said portion by way of locking means, and **in that** a plate (7a) of a material that is permeable to light radiation is fitted on said cartridge (7) proximate to said filter (12) and parallel thereto.
2. The unit according to claim 1, **characterized in that** said cartridge (7) is shaped substantially like a parallelepiped and is provided with front channels (8) and rear channels (8a) for the passage of air and with a plurality of electrical contacts (14) for connection to the handpiece (2).
 3. The unit according to claim 1, **characterized in that** said locking means are the walls of said half-shells (2a, 2b), which can be fastened to each other by means of an appropriate wrench (C), clamping said cartridge (7) within said portion of said chamber.
 4. The unit according to claim 1, **characterized in that** said locking means are threaded elements (2c), which are accommodated within through holes of said half-shells (2a, 2b) and can be turned by means of an appropriate wrench (C), fastening said cartridge (7) within said portion of said chamber.
 5. The unit according to claim 1, **characterized in that** said locking means are constituted by at least one toggle lever, which is articulated on one of said half-shells (2a), engages in a protrusion of the other half-shell (2b), and is suitable to hinder the exit of said cartridge (7) from said portion of said chamber.
 6. The unit according to claim 1, **characterized in that** said plate (7a) that is permeable to light radiation has two perimetric bands (7b), which are arranged at right angles thereto and are provided with end protrusions (7c) for anchoring to the side walls of said cartridge (7).
 7. The unit according to claims 1 and 6, **characterized in that** said cartridge (7) has, along its side walls, proximate to the open surface, from which said filter (12) can be accessed, two longitudinal grooves (7c), which are suitable to accommodate stably said protrusions (7b) of said plate (7).
 8. The unit according to claim 1, **characterized in that** said plate (7) is made of glassy material.
 9. The unit according to claim 1 and as an alternative to claim 8, **characterized in that** said plate (7) is made of crystalline material.
 10. The unit according to claim 1, **characterized in that** said plate (7) is made of polymeric material.
 11. The unit according to one or more of the preceding claims, **characterized in that** the emitted radiation has wavelengths comprised between 1 and 2000 nanometers.
 12. The unit according to one or more of the preceding claims, **characterized in that** inside said handpiece (1) and said cartridge (7), all the components are mounted so that they are mutually spaced in order to facilitate convection for cooling.
 13. The unit according to one or more of the preceding claims, **characterized in that** said handpiece (1) comprises a small electric motor, which drives a fan (19) that is installed upstream of a duct arranged inside the handpiece (2), which is connected to the outside at the front and at the rear of said handpiece (2); said motor, said fan (19) and said duct being suitable to cool said light source (17) installed in said cartridge (7).
 14. The unit according to one or more of the preceding claims, **characterized in that** said handpiece (2) comprises a hydraulic circuit, which is constituted by a continuous channel that is distributed along the handpiece and is connected, by means of a delivery tube and a return tube, to a refrigeration unit.
 15. The unit according to claim 1, **characterized in that** said light source (17) affects a rectangular skin treatment area which has an area of approximately 5 and 3 centimeters.
 16. The unit according to claim 1, **characterized in that** said cartridge (7) containing said light source (17) is provided with masks (10) for reducing the treatment area, which can be superimposed on said plate (7a).
 17. The unit according to claim 16, **characterized in that** said masks (10) are plates made of non-transparent material, which are provided with small openings and are installed on respective sliders along the lateral surfaces of the cartridge (7) that contains the light source (17), said masks being able to perform a translational motion and a rotation from a configuration in which they are parallel and proximate to said lateral surfaces to a configuration in which they are interposed between said light source (17) and the skin, reducing the illuminated area.





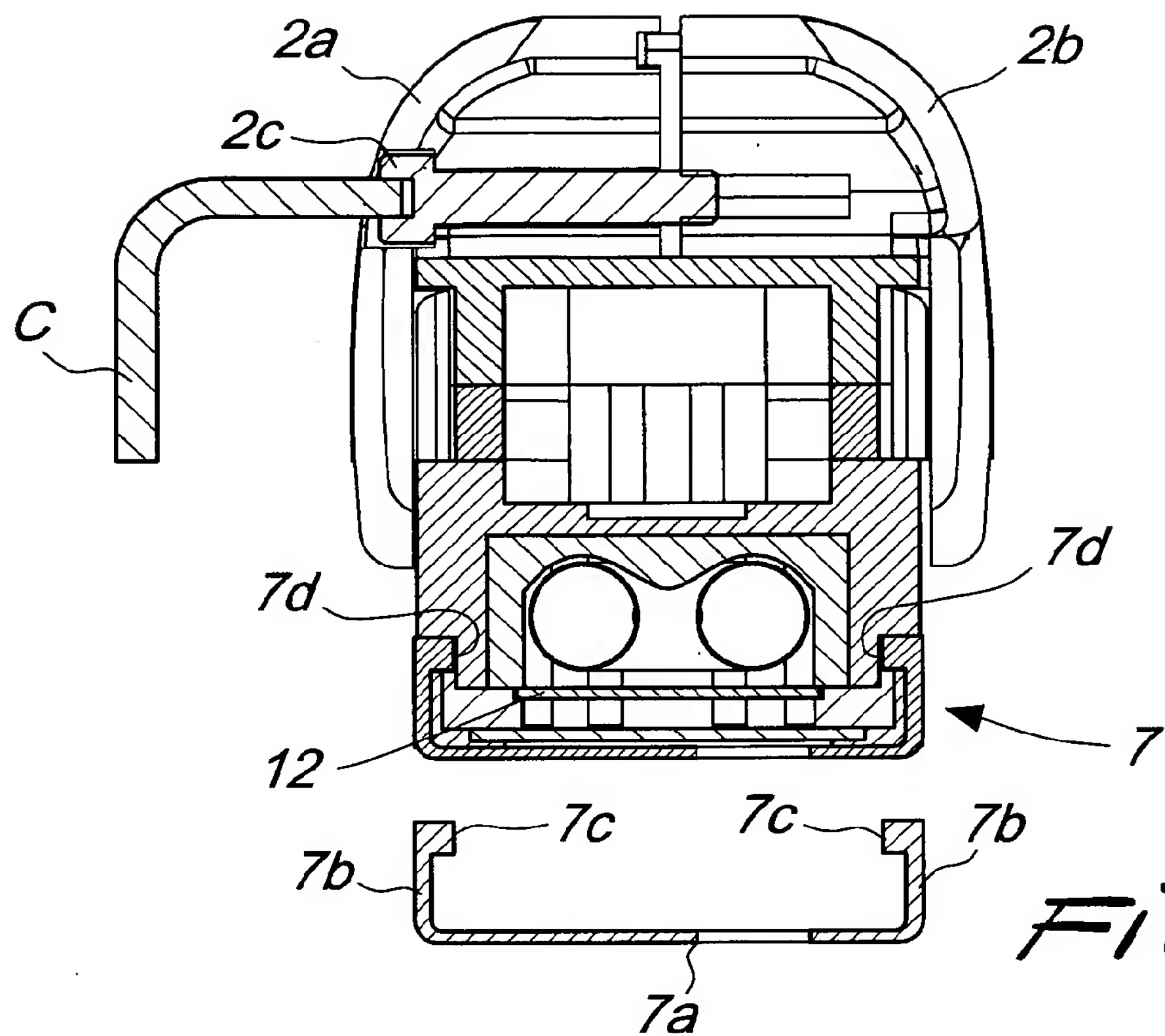


Fig. 4

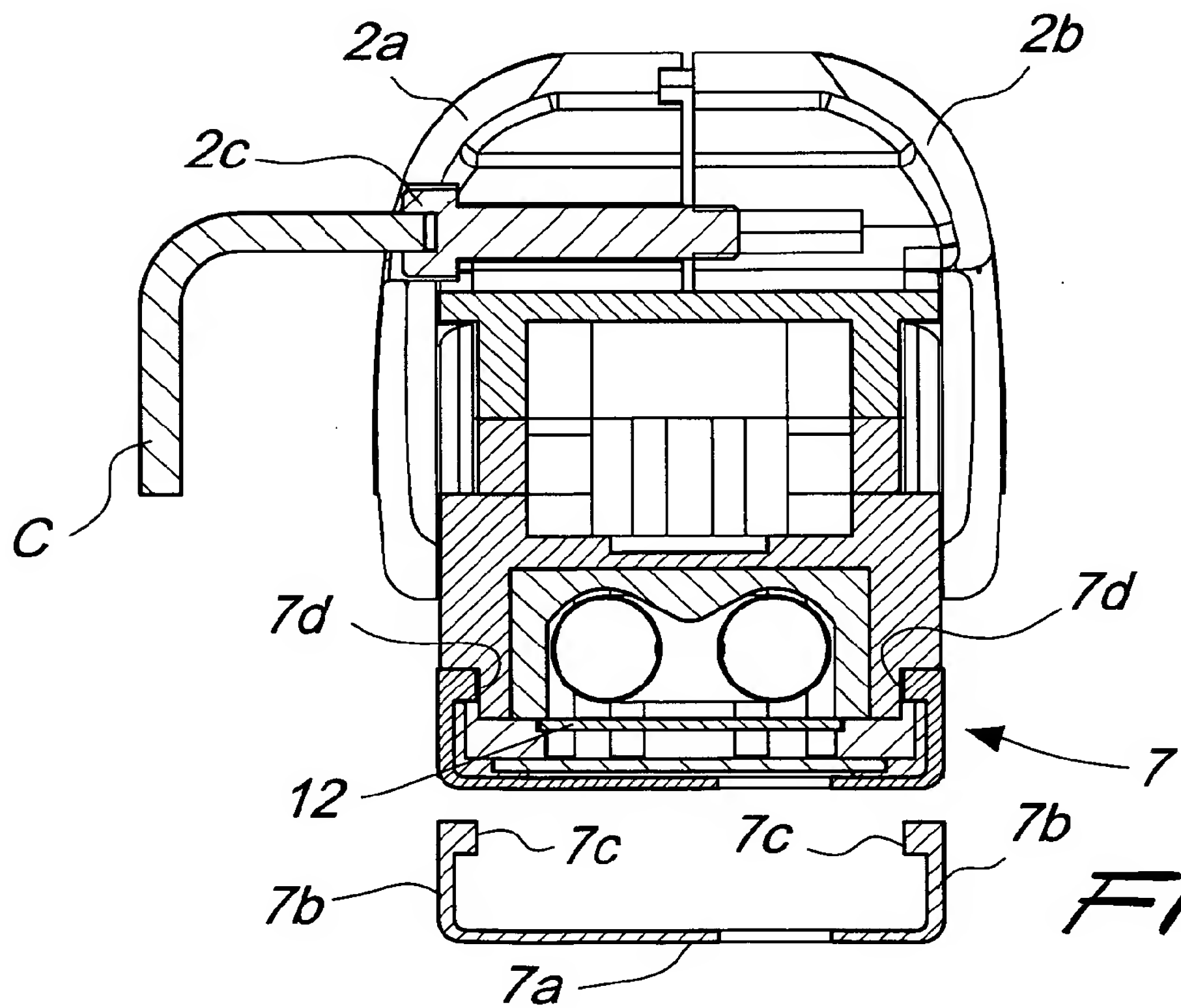
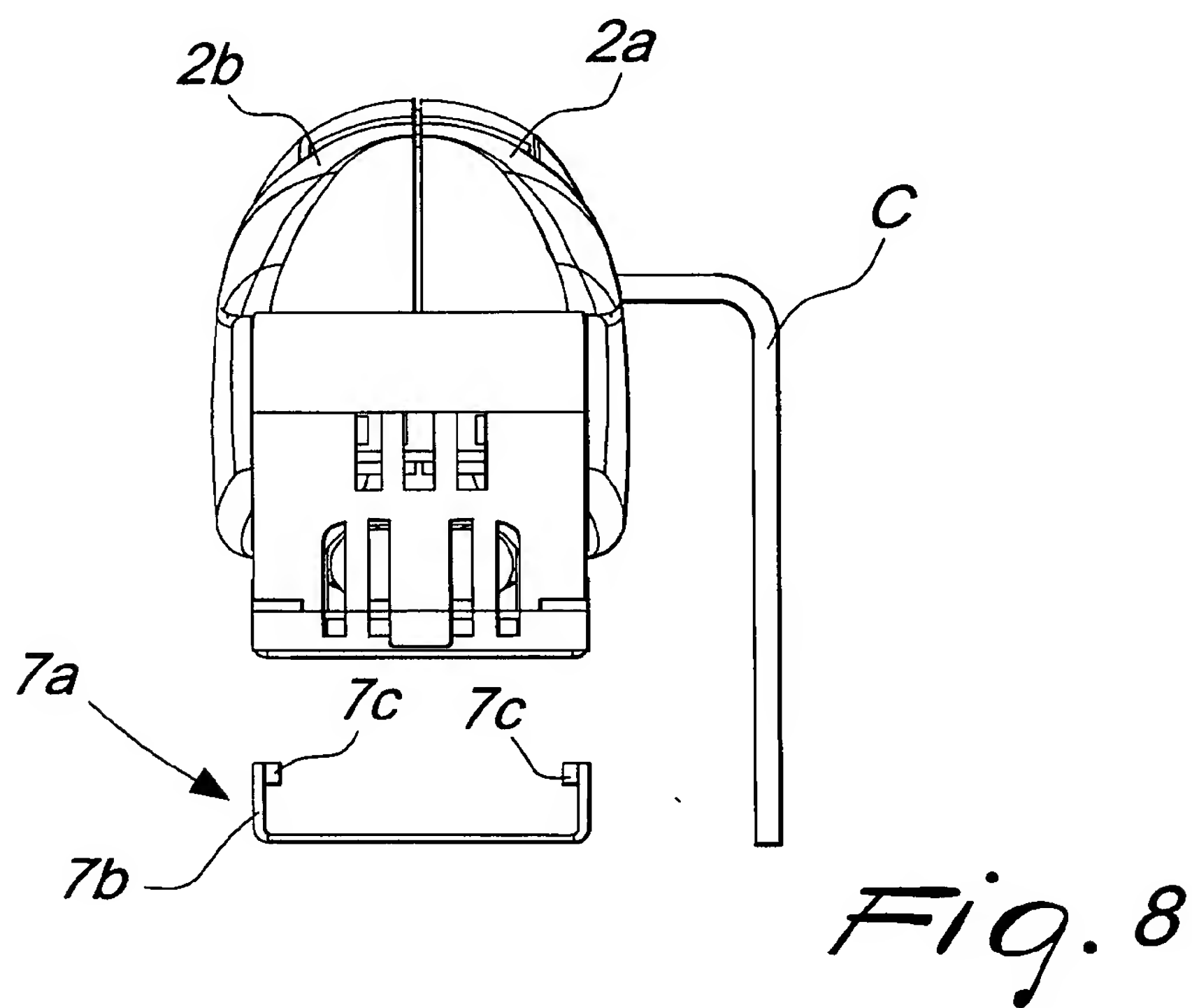
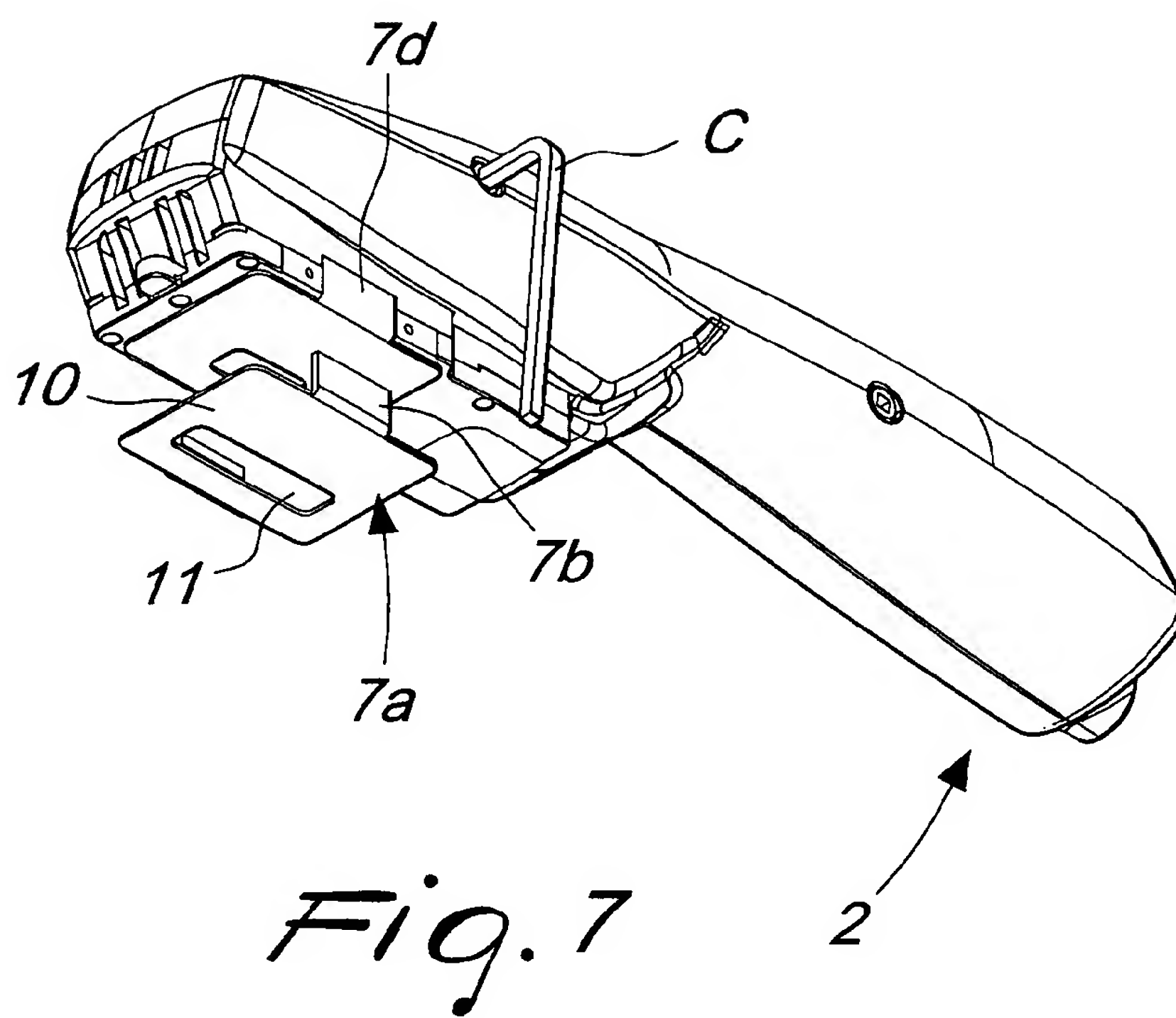
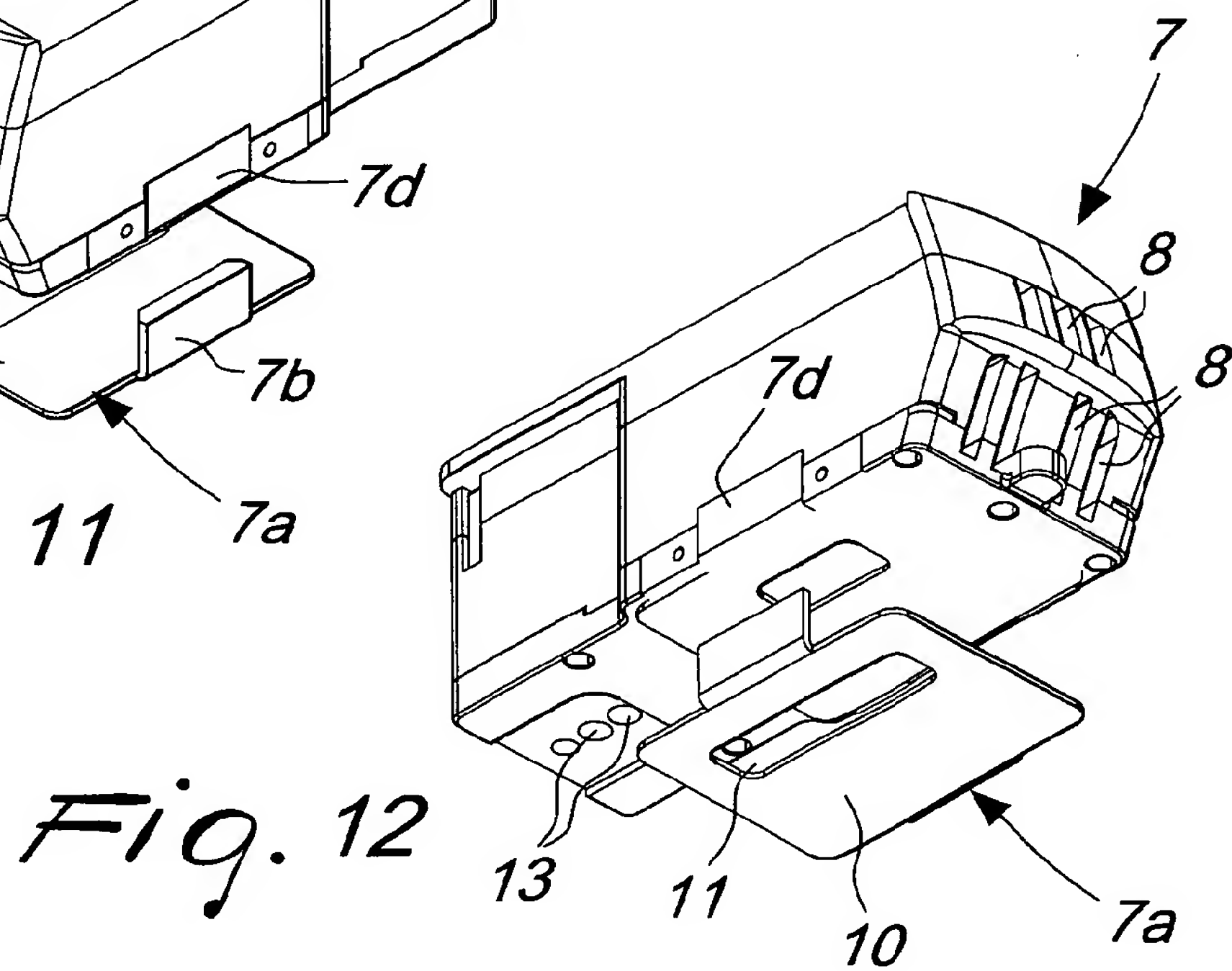
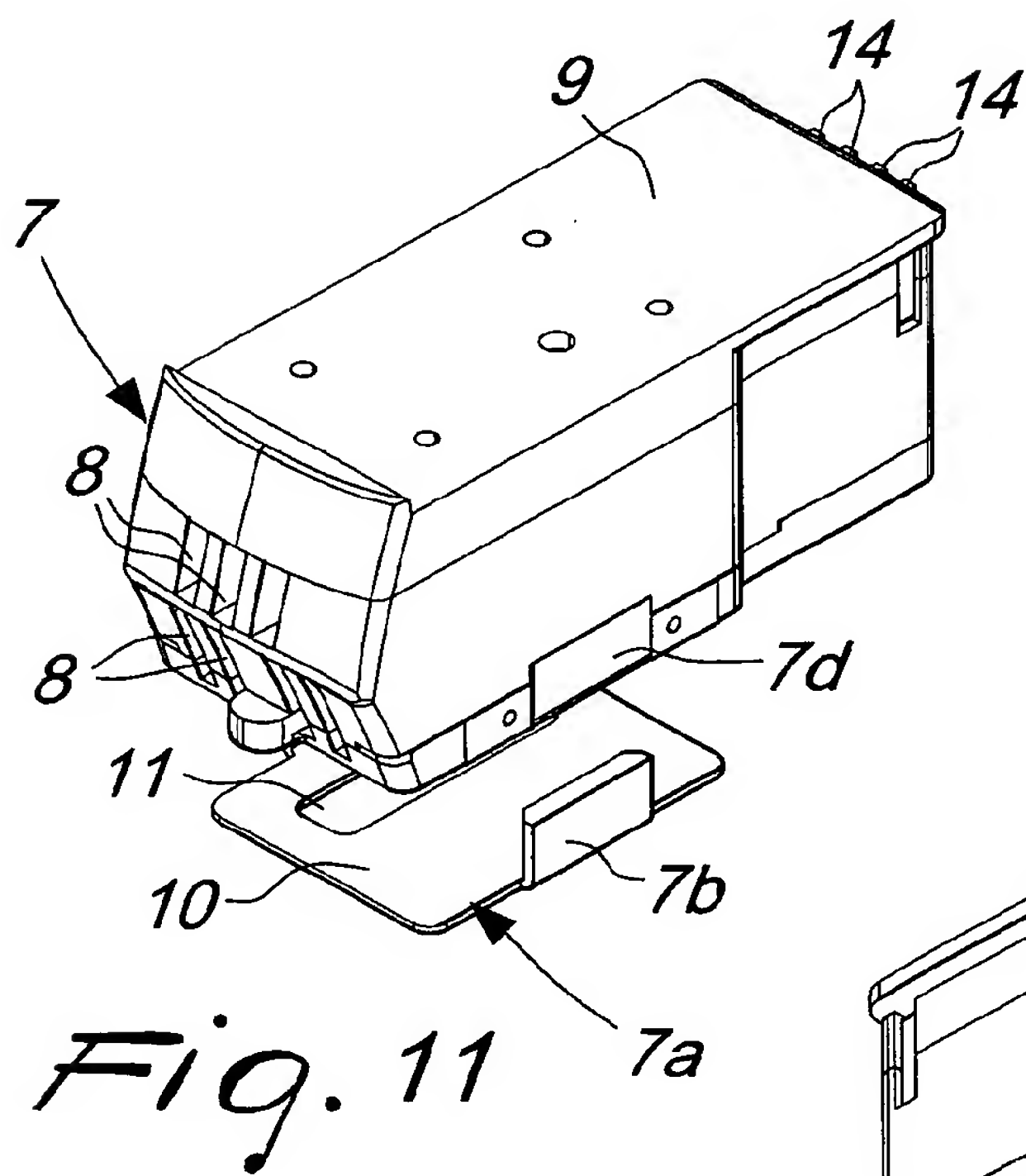
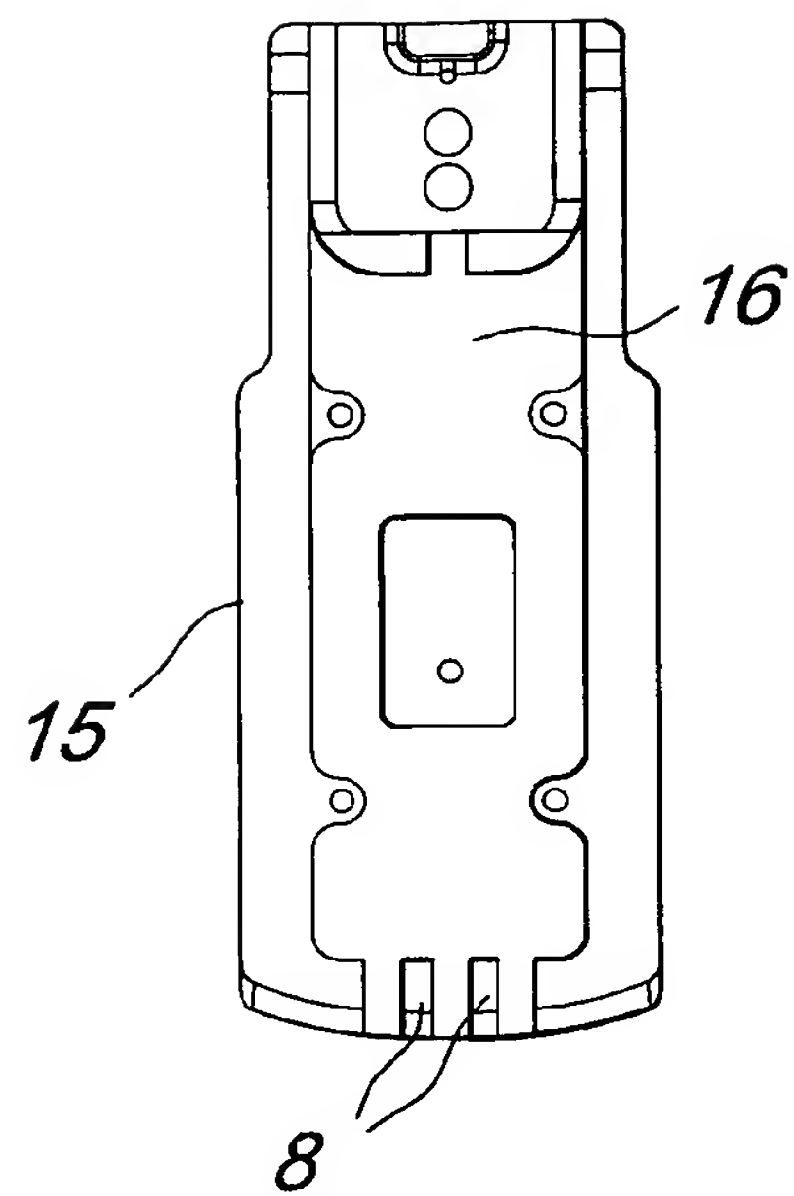
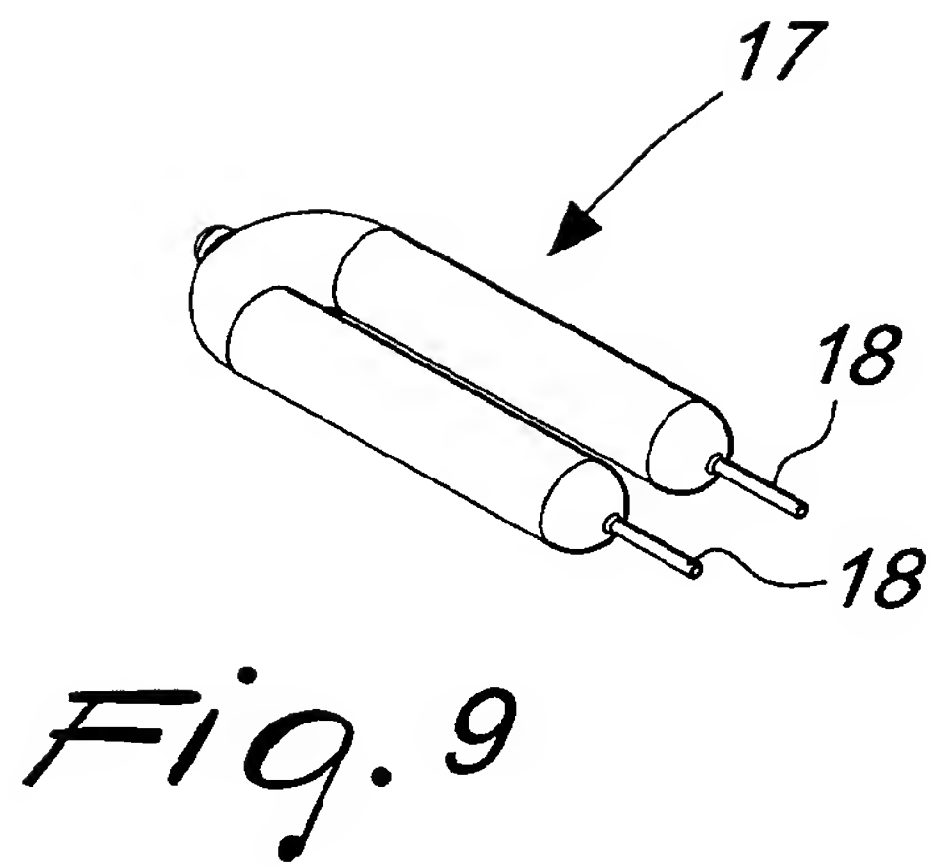


Fig. 5





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 04 02 5840

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	WO 03/043514 A (GENERAL PROJECT S.R.L; NALDONI, MORENO) 30 May 2003 (2003-05-30) * the whole document * * page 5, line 2 - page 6, line 19 * -----	1	A61B18/20
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A	WO 02/082866 A (EL.EN S.P.A; MODI, STEFANO) 17 October 2002 (2002-10-17) * claim 1 *	1	
T	WO 2004/096072 A (O.I. OESSE INTERNATIONAL S.R.L; MAGRI, MICHAEL) 11 November 2004 (2004-11-11) * the whole document * -----	1	
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The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 18 February 2005	Examiner Petter, E
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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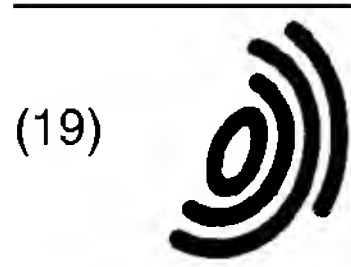
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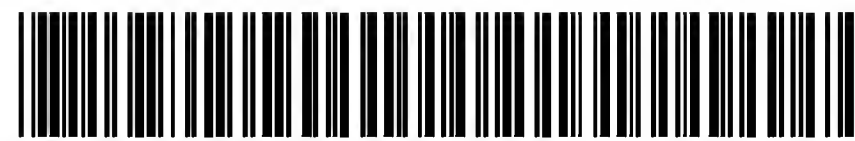
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(54) Apparatus for vacuum-assisted light-based treatments of the skin

(57) A method and apparatus are disclosed for enhancing the absorption of light in targeted skin structures. A vacuum chamber having a clear transmitting element transparent to intense pulsed light on its proximate end and an aperture on its distal end is placed on a skin target. After applying a vacuum to the vacuum chamber and modulating the applied vacuum, the concentration of blood and/or blood vessels is increased within a prede-

termined depth below the skin surface of the skin target. Optical energy associated with light directed in a direction substantially normal to a skin surface adjoining the skin target is absorbed within the predetermined depth. The apparatus is suitable for treating vascular lesions with a reduced treatment energy density level and pain sensation than that of the prior art and for evacuating condensed vapors produced during the cooling of skin prior to firing the light with a controlled delay.

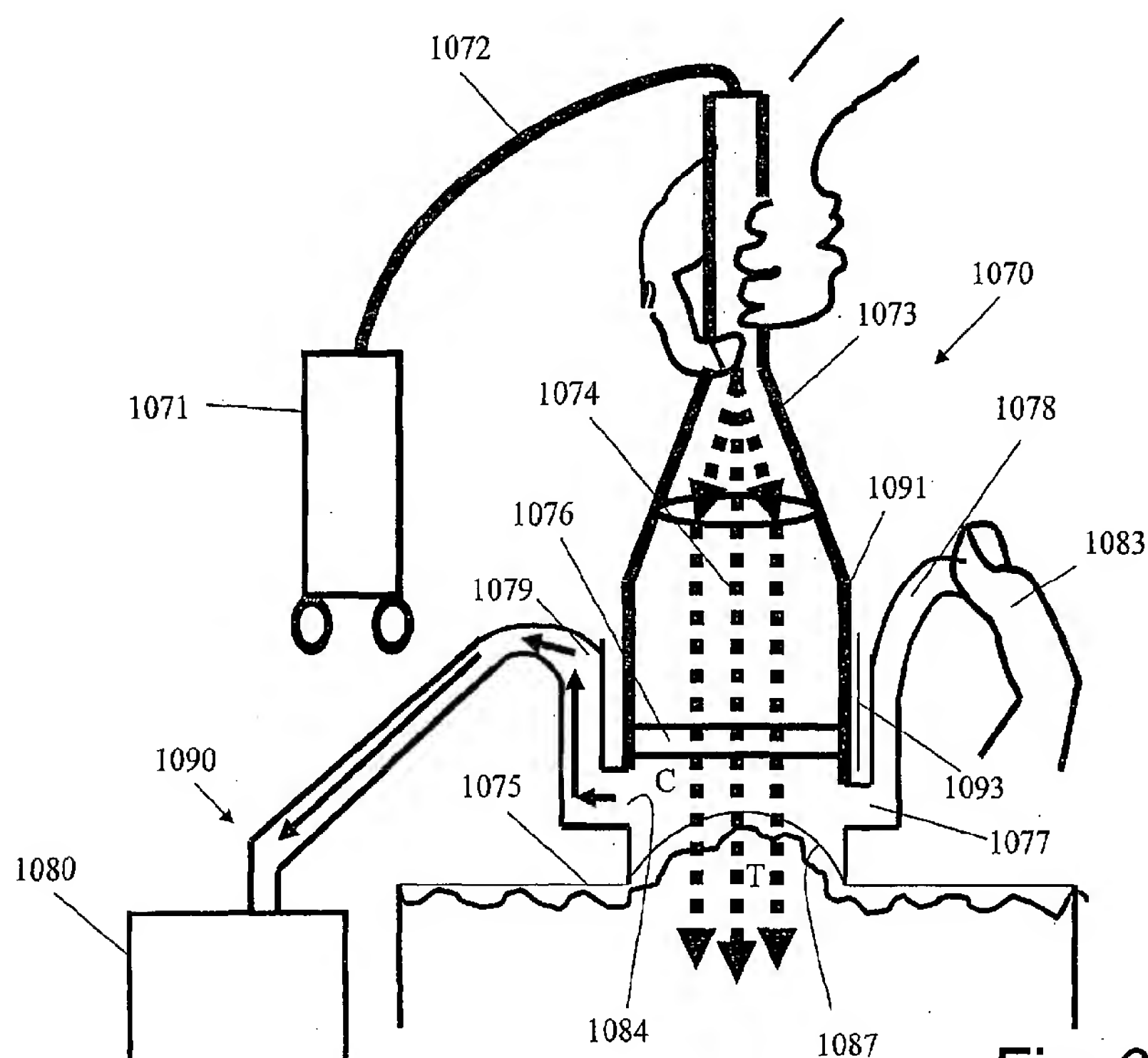


Fig. 6

Description

[0001] This application claims priority from US Patent Application 11/057,542 (filed February 14, 2005), which claims priority from Israeli Patent Application No. 160510 (filed on February 22, 2004), and from US Patent Application 10/498,382 (filed June 10, 2004), which is a Continuation-In-Part of PCT/IL02/00635 (filed on August 2, 2002), which is derived from IL 147009 (filed on December 10, 2001) and from IL 150094 (filed on June 6, 2002).

Field of the Invention

[0002] The present invention is related to the field of light-based skin treatments. More specifically, the invention is related to the utilization of light sources for the non-invasive treatment of skin disorders under the skin surface, whereby light is selectively absorbed by hair shafts, blood vessels, or collagen bundles, for the treatment or destruction of unwanted hairs, of blood vessels, or of other skin disorders.

Background of the Invention

[0003] Prior art very high intensity, short duration pulsed light systems which operate in the visible part of the spectrum, such as flashlamps or intense pulsed lasers are currently used in aesthetic treatments by one of two known ways: a) Applying the light to the skin without applying any pressure on the treatment zone, so as not to interfere with the natural absorption properties of skin; and b) Applying pressure onto the skin by means of the exit window of the treatment device in contact with the skin, thereby expelling blood from the light path within the skin and enabling better transmission of the light to a skin target in cases where the spectral lines of the treatment light source match absorption lines of the blood.

[0004] The major applications of intense pulsed light or intense pulsed laser systems are hair removal, coagulation of blood vessels for e.g. port wine stains, telangiectasia, spider veins and leg veins, multiple heating of blood vessels for e.g. rosacea, treatment of pigmented skin such as erasure of black stains and sun stains or tattoo removal, and removal of fine wrinkles by heating the tissue around the wrinkles, normally referred to as photorejuvenation.

[0005] US Patent Nos. 5,226,907, 5,059,192, 5,879,346, 5,066,293, 4,976,709, 6,120,497, 6,120,497, 5,626,631, 5,344,418, 5,885,773, 5,964,749, 6,214,034 and 6,273,884 describe various laser and non-coherent intense pulsed light systems. These prior art light systems are not intended to increase the natural absorption of the skin.

[0006] Applying a vacuum to the skin is a known prior art procedure, e.g. for the treatment of cellulites, which complements massaging the skin. Such a procedure produces a flow of lymphatic fluids so that toxic substances may be released from the tissue. As the vacuum is applied, a skin fold is formed. The skin fold is raised above the surrounding skin surface, and the movement of a handheld suction device across the raised skin performs the massage. The suction device is moved in a specific direction relative to the lymphatic vessels, to allow lymphatic fluids to flow in their natural flow direction. The lymphatic valve in each lymphatic vessel prevents the flow of lymphatic fluid in the opposite direction, if the suction device were moved incorrectly. Liquids generally accumulate if movement is not imparted to the raised skin. The massage, which is generally carried out by means of motorized or hand driven wheels or balls, draws lymphatic fluids from cellulite in the adipose subcutaneous region and other deep skin areas, the depth being approximately 5-10 mm below the dermis.

[0007] US Patent No. 5,961,475 discloses a massaging device with which negative pressure is applied to the skin together during massaging. A similar massaging device which incorporates a radio frequency (RF) source for the improvement of lymphatic flow by slightly heating the adipose tissue is described in US Patent No. 6,662,054. Some massaging systems, such as those produced by Deka and Cynosure, add a low power, continuous working (CW) light source of approximately 0.1-2 W/cm², in order to provide deep heating of the adipose tissue by approximately 1-3°C degrees and to enhance lymphatic circulation. The light sources associated with vacuum lymphatic massage devices are incapable of inducing blood vessel coagulation due to their low power. Also, prior art vacuum lymphatic massage devices are adapted to induce skin protrusion or to produce a skin fold by applying a vacuum.

[0008] Selective treatment of blood vessels by absorption of intense pulsed laser radiation is possible with Dye lasers operating at 585 nm, as well as with other types of lasers. Photorejuvenation has also been performed with Diode lasers in the near infrared spectral band of 800-980 nm and with Nd:YAG lasers having a frequency of approximately 1064 nm with limited success. The light emitted by such lasers is not well absorbed by tiny blood vessels or by the adjoining liquid. Broadband non-coherent intense pulsed light systems are also utilized for photorejuvenation with some success, although requiring more than 10 repeated treatments. The heat which is absorbed by the blood vessels, as a result of the light emitted by the intense short pulse devices, is transferred to adjacent collagen bundles.

[0009] The absorption of pulsed Diode and Nd:YAG laser beams by blood vessels is lower than the absorption of pulsed Dye laser beam. In order to compensate for limited photorejuvenation with red and infrared intense pulsed light and laser systems, a very high energy density as high as 30-60 J/cm² needs to be generated. At such an energy density, the melanin-rich epidermis, particularly in dark skin, is damaged if not chilled. A method to reduce the energy density of

intense pulsed lasers or non-coherent intense pulsed light sources which operate in the visible or the near infrared regions of the spectrum will therefore be beneficial.

[0010] Pulsed dye lasers operating in the yellow spectral band of approximately 585-600 nm, which is much better absorbed by blood vessels, are also utilized for the smoothing of fine wrinkles. The energy density of light emitted by Dye lasers, which is approximately 3-5 J/cm², is much lower than that of light emitted by other lasers. However, the pulse durations of light emitted by Dye lasers are very short, close to 1 microsecond, and therefore risk the epidermis in darker skin. Treatments of wrinkles with Dye lasers are slow, due to the low concentration of absorbing blood vessels, as manifested by the yellow or white color of treated skin, rather than red or pink characteristic of skin having a high concentration of blood vessels. Due to the low energy density of light emitted by Dye lasers, as many as 10 treatments may be necessary. A method to reduce the energy density of light generated by Dye lasers, or to reduce the number of required treatments at currently used energy density levels, for the treatment of fine wrinkles, would be beneficial.

[0011] Pulsed Dye lasers operating at 585 nm are also utilized for the treatment of vascular lesions such as port wine stains or telangiectasia or for the treatment of spider veins. The energy density of the emitted light is approximately 10-15 J/cm², and is liable to cause a burn while creating the necessary purpura. A method to reduce the energy density of light emitted by Dye lasers for the treatment of vascular lesions would be highly beneficial.

[0012] Hair removal has been achieved by inducing the absorption of infrared light, which is not well absorbed by melanin present in hair strands, impinging on blood vessels. More specifically, absorption of infrared light by blood vessels at the distal end of hair follicles contributes to the process of hair removal. High intensity pulsed Nd:YAG lasers, such as those produced by Altus, Deka, and Iridex, which emit light having an energy density of more than 50 J/cm², are used for hair removal. The light penetration is deep, and is often greater than 6 millimeters. Some intense pulsed light or pulsed laser systems, such as that produced by Syneron, used for hair removal or photorejuvenation also employ an RF source for further absorption of energy within the skin.

[0013] The evacuation of smoke or vapor, which is produced following the impingement of monochromatic light on a skin target, from the gap between the distal end window of a laser system and the skin target, is carried out in conjunction with prior art ablative laser systems such as CO₂, Erbium or Excimer laser systems. The produced smoke or vapor is usually purged by the introduction of external fresh air at greater than atmospheric pressure.

[0014] Coagulative lasers such as pulsed dye lasers or pulsed Nd:YAG lasers, which treat vascular lesions under the skin surface without ablating the skin surface, are generally not provided with an evacuation chamber which produces subatmospheric pressure over a skin target.

[0015] Some prior art intense pulsed laser systems, which operate in the visible and near infrared region of the spectrum and treat lesions under the skin surface, e.g. vascular lesions, with pulsed dye laser systems or pulsed Nd:YAG lasers, employ a skin chilling system. Humidity generally condenses on the distal window, due to the use of a skin chilling system. The humidity is not caused by the skin treatment, but rather by the low temperature of the distal window. It would be advantageous to evacuate the condensed vapors from the distal window of the laser system prior to the next firing of the laser.

[0016] US Patent Nos. 5,595,568 and 5,735,844 describe a coherent laser system for hair removal whereby pressure is applied to the skin by a transparent contact device in contact therewith, in order to expel blood present in blood vessels from a treatment zone. In this approach blood absorption decreases in order to increase subcutaneous light penetration.

[0017] US Patent Nos. 5,630,811 and 5,853,407 also describe a coherent laser system for hair removal which restricts local blood flow, in order to reduce damage to the skin tissue surrounding the hairs. Local tissue structures are flattened by applying positive pressure or negative pressure to the skin. The treatment beam is limited to only 5 mm. The treatment beam is not suitable for a larger treatment spot per pulse of approximately 40 mm. Blood expulsion is not uniform and not instantaneous for such large treatment spots, and therefore blood may remain in the skin tissue after the laser beam has been fired. Also, a large-diameter treatment device may not be easily repositioned to another treatment site, due to the relatively high lifting force needed when negative pressure is applied to the skin. Furthermore, this laser system does not provide any means for preventing gel obstruction when negative pressure is applied to the skin. Although applying a flattening positive pressure or negative pressure to a small-diameter treatment area enhances hair removal, the treatment of vascular lesions is not improved since fewer blood vessels are present within the treatment area due to the blood expulsion. A need therefore exists for a vacuum-assisted device that can alternatively reduce or increase the blood volume fraction within a skin target.

[0018] The light-based non-ablative treatment of hair or of vascular lesions is often very painful, particularly during the treatment of dark and thick unwanted hairs which may appear in a bikini line, on the legs, or on the back. A pain sensation is felt with almost all types of light based devices for hair removal, including intense pulsed light sources and lasers.

[0019] The aforementioned prior art efforts to expel blood vessels help in some cases to avoid unnecessary damage to skin structures which are not intended to be treated, such as unnecessary coagulation of blood vessels during a hair removal treatment, while increasing hair removal efficacy. The reduction in damage to skin structures does not alleviate the immediate pain sensed during a treatment, but rather, the expulsion of blood causes a higher exposure of the hair

shaft to a treatment pulse of light, resulting in a higher hair follicle temperature and a correspondingly higher level of acute pain due to excessive heating of the nerves which surround the hair shafts. Furthermore, the expelling of blood from one skin area increases the fractional blood volume in adjacent areas, causing a risk of thermal damage if the treatment light diffuses to the adjacent blood rich zone. It is well known to light-based hair removal practitioners that acute pain is felt during the treatment when hairy areas, particularly characterized by dark thick hair, are impinged by the treatment beam, whereas firing the light beam on a hairless area is substantially painless. It can therefore be concluded that the pain which is sensed during a hair removal treatment is generated by nerves surrounding the hair shafts, and not by nerves distributed in other areas of the skin. There is therefore a need for an improved apparatus for pain reduction without having to reduce the treatment energy density.

[0020] Two types of a pain sensation caused by light-based aesthetic treatments are recognizable: immediate sharp pain and long term milder pain. The immediate sharp pain is felt during each treatment pulse and increases to an intolerable sensation after a few shots, necessitating a patient to rest during a long delay before continuing the treatment. The treatment rate, particularly for large areas such as on the legs, is therefore considerably reduced. Depending on his pain tolerance, the patient may even decide not to continue the treatment. The sharp pain is caused by the exposure of treatment light to nerve endings located in the epidermis and dermis, by sensory receptors of hair shafts located deep in the dermis, or by the stimulation of nerves surrounding the hair bulbs as the hair shafts are being heated during the treatment, often at a temperature of approximately 70°C.

[0021] The less acute, long term milder pain is caused by the accumulative increase of skin temperature following treatment, e.g. during a period ranging from 10 minutes to a day after treatment, which is approximately 3 to 5 °C above body temperature. The increase in skin temperature may induce redness and edema, causing pain, depending on the hair density and the fractional blood volume within the adjoining tissue. The application of a cold gauze immediately after the treatment usually helps to avoid the post-treatment pain.

[0022] The most common prior art method for alleviating or preventing the immediate sharp pain caused by the non-ablative treatment of hair or of vascular lesions with intense pulsed light is the application of EMLA cream produced by AstraZeneca Canada Inc. Such cream is a topical anesthetic applied to the skin approximately 30-60 minutes before a treatment, which numbs the skin and decreases the sensation of pain. This prior art method is generally impractical due to the long and inconvenient waiting time between the application of the EMLA cream and the treatment. Since health professionals prefer to maximize the number of patients to be treated during a given time period, the health clinic must provide a large waiting room for those patients that are waiting to be treated by intense pulsed light following the application of the EMLA cream.

[0023] Pain caused by the non-ablative treatment of hair or of vascular lesions may also be alleviated or prevented by reducing the energy density of the intense pulsed light. Energy density reduction, however, compromises the treatment quality, and therefore is an unacceptable solution, particularly due the relatively high cost of treatment.

[0024] US Patent Nos. 6,264,649 and 6,530,920 disclose a cooling head for a skin treatment laser and a method to reduce or eliminate pain during laser ablative treatments of the skin by cooling the skin surrounding the treatment area. The pain is associated with the ablation or burning of a skin surface during skin resurfacing. An extraction port of the cooling head enables removal of debris material, such as smoke produced by the skin treatment laser, from the treatment area and for connection to a vacuum source. Evacuated vapor such as smoke is replaced by fresh and clean air.

[0025] With respect to prior art smoke evacuation devices, a significant subatmospheric pressure is generally not generated over a skin surface due to the introduction of fresh atmospheric pressure air. If subatmospheric pressure were maintained over a skin surface, the treatment handpiece would be prevented from being lifted and displaced from one skin site to another during the treatment process. Additionally, prior art smoke evacuation devices are not associated with non-ablative lasers, such as a long-pulse Nd:YAG laser, which treat tissue only under the skin surface and do not produce smoke resulting from the vaporization of the skin surface. Furthermore, the application of heat releasing gel onto a skin target is not conducive for the ablation of a skin surface or for the subsequent evacuation of debris material since the gel forms a barrier between the skin surface and the surrounding air.

[0026] Current laser and IPL skin treatment systems utilize chilling means. However, pain is still noticeable.

[0027] A need therefore exists for alleviating the resulting pain caused by the treatment of unwanted hair, unwanted wrinkles or vascular lesions by intense pulsed light or intense pulsed laser systems, without reducing the light source intensity, without applying a topical anesthetic, and without using a chiller as means to reduce pain.

[0028] It is an object of the present invention to provide a method and apparatus for the treatment of subcutaneous lesions, such as vascular lesions, by a non-ablative, high intensity pulsed laser or light system operating at wavelengths shorter than 1800 nm which does not damage the surface of the skin or the epidermis.

[0029] It is an object of the present invention to provide a method and apparatus for controlling the depth of subcutaneous light absorption.

[0030] It is an object of the present invention to provide a method and apparatus for increasing the absorption of light which impinges a skin target by increasing the concentration of blood vessels thereat.

[0031] It is an additional object of the present invention to provide a method and apparatus by which the energy density

level of intense pulsed light that is suitable for hair removal, fine wrinkle removal, including removal of wrinkles around the eyes and in the vicinity of the hands or the neck, and the treatment of port wine stain or rosacea may be reduced relative to that of the prior art.

[0032] It is an additional object of the present invention to provide a method and apparatus by which the number of required treatments for hair removal, fine wrinkle removal, including removal of wrinkles around the eyes and in the vicinity of the hands or the neck, and the treatment of port wine stain or rosacea at currently used energy density levels may be reduced relative to that of the prior art.

[0033] It is yet an additional object of the present invention to provide a method and apparatus for repeated evacuation, prior to the firing of a subsequent light pulse, of vapors which condense on the distal window due to the chilling of laser treated skin.

[0034] It is yet an additional object of the present invention to provide a method and apparatus for alleviating the resulting pain caused by the treatment of unwanted hair, unwanted wrinkles or vascular lesions by intense pulsed light or intense pulsed laser systems, without reducing the light source intensity, without applying a topical anesthetic, and without relying on skin chilling for pain reduction.

[0035] It is yet an additional object of the present invention to provide a method and apparatus for speedy repositioning of a vacuum-assisted, non-ablative light-based treatment handpiece from one site to another.

[0036] It is yet an additional object of the present invention to provide a method and apparatus for a vacuum-assisted, light-based skin treatment which is conducive for the application of a heat releasing gel onto a skin surface, without resulting in obstruction of vacuum generating apparatus.

[0037] It is a further object of the present invention to provide an apparatus for vacuum-assisted, light-based treatment which can be held by one hand while a light treatment handpiece is held by the other hand.

[0038] Other objects and advantages of the invention will become apparent as the description proceeds.

Summary of the Invention

[0039] The present invention is directed to apparatus for vacuum-assisted light-based skin treatments. The apparatus comprises a vacuum chamber which is transparent or translucent to intense pulsed monochromatic or non-coherent light directed to a skin target. A vacuum is applied to said vacuum chamber, whereby said skin target is drawn to said vacuum chamber. The efficacy and utility of the apparatus are achieved by employing the apparatus in two modes: (a) in a vacuum applying mode wherein a high vacuum level ranging from 0-1 atmospheres is attained and (b) in a vacuum release mode upon deactivation of the light source and of the vacuum pump after optical energy associated with the directed light has been absorbed within a predetermined depth under the skin surface, wherein atmospheric air is introduced to the vacuum chamber so that the vacuum chamber may be speedily repositioned to another skin target.

[0040] In one embodiment of the invention, the apparatus comprises:

- a) a non-ablative intense pulsed monochromatic or non-coherent light source;
- b) a vacuum chamber placeable on a skin target which has an opening on the distal end thereof and provided with a clear transmitting element on the proximate end thereof, said transmitting element being transparent or translucent to light generated by said source and directed to said skin target;
- c) means for applying a vacuum to said vacuum chamber, the level of the applied vacuum suitable for drawing said skin target to said vacuum chamber via said opening; and
- d) means for preventing influx of air into vacuum chamber during a vacuum applying mode.

[0041] As referred to herein, "distal" is defined as a direction towards the exit of the light source and "proximate" is defined as a direction opposite from a distal direction.

[0042] The terms "evacuation chamber" and "vacuum chamber" as referred to herein are interchangeable.

[0043] The vacuum chamber is advantageously one-hand graspable by means of a handle connected thereto so that the vacuum chamber can be held by one hand while a light treatment handpiece is held by the other hand.

[0044] Preferably-

- a) the vacuum applying means comprises a vacuum pump and at least one control valve;
- b) the wavelength of the light ranges from 400 to 1800 nm;
- c) the pulse duration of the light ranges from 10 nanoseconds to 900 msec;
- d) the energy density of the light ranges from approximately 2 to approximately 150 J/ cm²;
- e) the level of applied vacuum within the vacuum chamber ranges from approximately 0 to approximately 1 atmosphere;
- f) the light source is selected from the group of Dye laser, Nd:YAG laser, Diode laser, light emitting diode, Alexandrite laser, Ruby laser, Nd:YAG frequency doubled laser, Nd:Glass laser, a non-coherent intense pulse light source, and

a non-coherent intense pulse light source combined with an RF source;

g) the light is suitable for hair removal, collagen contraction, photorejuvenation, treatment of vascular lesions, treatment of sebaceous or sweat glands, treatment of warts, treatment of pigmented lesions, treatment of damaged collagen, treatment of acne, treatment of warts, treatment of keloids, treatment of sweat glands, and treatment of psoriasis;

h) the light is suitable for the treatment of vascular lesions selected from the group of port wine stains, telangiectasia, rosacea, and spider veins;

i) the clear transmitting element is suitable for transmitting the light in a direction substantially normal to a skin surface adjoining said skin target;

j) the clear transmitting element is separated from the adjoining skin surface by a gap ranging from 0.5 to 50 mm, and preferably approximately 2 mm;

k) the treatment spot per pulse is greater than 5 mm, and preferably between 15 to 50 mm;

l) the influx of air into vacuum chamber during a vacuum applying mode is prevented by means of a control valve and control circuitry or by means of manual occlusion of a vacuum chamber conduit;

m) the ratio of the maximum length to maximum width of the aperture formed on the distal end of the vacuum chamber ranges from approximately 1 to 4;

n) the vacuum chamber has at least one suction opening, the vacuum being applied to the vacuum chamber via said at least one suction opening;

o) the vacuum chamber is U-shaped; and

p) the vacuum chamber is provided with a rim for sealing the peripheral contact area between the skin surface adjoining the skin target and the vacuum chamber wall.

[0045] Preferably, the apparatus further comprises control means for controlling operation of the vacuum pump, the at least one control valve, and the light source. The control means is selected from the group of electronic means, pneumatic means, electrical means, and optical means. The control means may be actuated by means of a finger depressable button, which is positioned on a light treatment handpiece.

[0046] In one aspect, the control means is suitable for firing the light source after a first predetermined delay, e.g. from approximately 0.5 sec to approximately 4 seconds, following operation of the vacuum pump.

[0047] In one aspect, the control means is suitable for firing the light source after a predetermined delay following opening of the at least one control valve.

[0048] In one aspect, the control means is suitable for increasing the pressure in the vacuum chamber to atmospheric pressure following deactivation of the light source, to allow for effortless repositioning of the vacuum chamber to a second skin target. The increase in vacuum chamber pressure may be triggered by means of a light detector which transmits a signal to the control means upon sensing a significant decrease in optical energy generated by the light source or may be effected after a second predetermined delay, following deactivation of the light source.

[0049] In one aspect, the control means is suitable for verifying that a desired energy density level of the light is being directed to the skin target and for deactivating the light source if the energy density level is significantly larger than said desired level.

[0050] In one aspect, the vacuum chamber is connected to, or integrally formed with, a proximately disposed handpiece through which light propagates towards the skin target. The vacuum chamber has a proximate cover formed with an aperture, said cover being attachable or releasably attachable to a handpiece such as a light guide having an integral clear transmitting element.

[0051] In one aspect, the vacuum pump is an air pump.

[0052] In one aspect, the vacuum pump is a peristaltic pump for drawing air and gel from the interior of the vacuum chamber via a hose connected to a conduit in communication with the interior of the vacuum chamber.

[0053] The hose provides indication means that the skin target has undergone a light-based treatment by means of gel which is discharged from an end of the hose onto a skin surface during a vacuum applying mode.

[0054] In one aspect, the apparatus further comprises means to stabilize the vacuum chamber on a substantially non-planar skin surface.

[0055] In one aspect, the apparatus further comprises a skin contact detector for sensing the placement of the vacuum chamber onto the skin target and for generating a first signal to activate the vacuum pump following placement of the vacuum chamber onto the skin target.

[0056] In one aspect, the control valve is opened following generation of a second signal by means of a light detector which is adapted to sense termination of the light directed to the skin target, atmospheric pressure air thereby being introduced to the interior of the vacuum chamber.

[0057] In one aspect, the second signal is suitable for deactivating the vacuum pump.

[0058] In another embodiment of the invention, the apparatus further comprises an array of vacuum chambers placeable on a skin surface. The array is formed from a single sheet made of material which is transparent or translucent to

the light, said sheet being formed with a plurality of conduits for air evacuation such that each of said conduits is in communication with a corresponding vacuum chamber. The distance between adjacent vacuum chambers is sufficiently small to allow light which has diffused from the interior of each chamber to treat a skin area located underneath a corresponding conduit.

5 **[0059]** Each conduit preferably branches into first and second portions which are in communication with a vacuum pump and with a source of compressed air, respectively.

[0060] In one aspect, each vacuum chamber is provided with a contact detector for triggering a signal to activate the vacuum pump, two control valves to control the passage of fluid through the corresponding first and second conduits portions, respectively, and a light detector which generates a signal to introduce compressed air through the correspond-
10 ing second conduit portion upon sensing the termination of the light directed to the skin target.

[0061] In one aspect, the first conduit portions are arranged such that the air from all vacuum chambers is evacuated simultaneously upon activation of the vacuum pump.

[0062] In another embodiment of the invention, the vacuum applying means comprises a vertically displaceable cover to which the clear transmitting element is secured and chamber walls which surround, and are of a similar shape as,
15 said cover, a vacuum being generated within a vacuum chamber defined by the volume between said cover, said walls, and the skin target upon proximal displacement of said cover relative to said walls. The means for preventing influx into the vacuum chamber is a sealing element which is secured to the outer periphery of the cover and resiliently contacts the chamber walls.

[0063] In one aspect, a proximally directed force or distally directed force is generated by any means selected from
20 the group of a plurality of solenoids, a spring assembly, and a pneumatic device, or a combination thereof, which are deployed around the periphery of the cover and connected to the walls, and is controllable so as to adjust the height of the drawn skin target relative to the adjoining skin surface. Due to their low power consumption, a 1.5 V battery may be used to energize the solenoids.

[0064] The apparatus preferably further comprises an aeration tube for introducing atmospheric air to the vacuum
25 chamber during a vacuum release mode. The aeration tube is in communication with a valve which is actuated upon conclusion of a skin target treatment.

[0065] In one aspect, the proximally directed force is supplemented by means of a vacuum pump.

[0066] In another embodiment of the invention, the apparatus comprises means for preventing passage of skin cooling gel to the vacuum applying means.

30 **[0067]** In one aspect, the means for preventing passage of gel to the vacuum applying means comprises a trap, a first conduit through which gel and air are drawn from the vacuum chamber to said trap, a second conduit through which air is drawn from said trap to the vacuum pump, and optionally, a filter at the inlet of the first and second conduits.

[0068] In one aspect, the trap is suitable for the introduction therein of an ion exchange resin with which the gel is boundable.

35 **[0069]** In one aspect, the means for preventing passage of gel is a detachable vacuum chamber upper portion, detachment of said upper portion allowing removal of gel retained within the vacuum chamber interior. Suitable apparatus comprises an upper portion having an open central area, a clear transmitting element attached to said upper portion, vacuum chamber walls, a vacuum chamber cover perpendicular to said walls and suitably sized so as to support said upper portion, and a plurality of attachment clips pivotally connected to a corresponding vacuum chamber wall for detachably securing said upper portion to said vacuum chamber cover.
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[0070] In one aspect, the vacuum chamber walls are coated with a hydrophobic material. Accordingly, the vacuum chamber provides indication that the skin target has undergone a light-based treatment by means of gel which falls to the skin surface during a vacuum release mode in the shape of the distal end of the vacuum chamber walls.

45 **[0071]** In one aspect, the at least one suction opening is sufficiently spaced above the distal end of a vacuum chamber wall and from the centerline of the vacuum chamber so as to prevent obstruction of the at least one suction opening by gel and drawn skin upon application of the vacuum.

[0072] In another embodiment of the invention, the apparatus further comprises means for skin cooling, said skin cooling means adapted to reduce the rate of temperature increase of the epidermis at the skin target. The level of the applied vacuum is suitable for evacuating condensed vapors which are produced within the gap between the clear
50 transmitting element and the skin target and condense on the clear transmitting element during the cooling of skin.

[0073] In one aspect, the skin cooling means is a metallic plate in abutment with the vacuum chamber on the external side thereof, said plate being cooled by means of a thermoelectric cooler. The plate may be positionable on the skin surface adjoining said skin target in order to cool the lateral sides of the vacuum chamber or may be in contact with the clear transmitting element.

55 **[0074]** In one aspect, the skin cooling means is a polycarbonate layer transparent to the directed light which is attached to the distal face of the clear transmitting element.

[0075] In one aspect, the skin cooling means is a gel, a low temperature liquid or gas applied onto the skin target.

[0076] In another embodiment of the invention, the apparatus is suitable for controlling the depth of light absorption

by blood vessels under a skin surface, comprising:

- a) a vacuum chamber placed on a skin target which is formed with an aperture on the distal end thereof and provided with a clear transmitting element on the proximate end thereof, said transmitting element being transparent or translucent to intense pulsed monochromatic or non-coherent light directed to said skin target and suitable for transmitting the light in a direction substantially normal to a skin surface adjoining said skin target;
- b) means for applying a vacuum to said vacuum chamber, the level of the applied vacuum suitable for drawing said skin target to said vacuum chamber via said aperture; and
- c) means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target, optical energy associated with the directed light being absorbed within said predetermined depth.

[0077] As referred to herein, the term "blood volume fraction" is interchangeable with "the concentration of blood and/or blood vessels within a predetermined depth below the skin surface".

[0078] In one embodiment, the means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target is a means for modulating the applied vacuum.

[0079] The depth under the skin surface at which optical energy is absorbed may be selected in order to thermally injure or treat predetermined skin structures located at said depth. As referred to herein, a "skin structure" is defined as any any damaged or healthy functional volume of material located under the epidermis, such as blood vessels, collagen bundles, hair shafts, hair follicles, sebaceous glands, sweat glands, adipose tissue. Depending on the blood concentration within the skin target, the light may propagate through the skin surface and upper skin layers without being absorbed thereat and then being absorbed at a skin layer corresponding to that of a predetermined skin structure. As referred to herein, the term "light" means both monochromatic and non-coherent light. The terms "light absorption" and "optical energy absorption" refer to the same physical process and are therefore interchangeable.

[0080] In contrast with a prior art vacuum-assisted apparatus for laser or intense pulsed light treatment wherein a sharp skin fold is produced through a slit following application of the vacuum, vacuum-assisted drawn skin by means of the apparatus of the present invention is not distorted, but rather is slightly and substantially uniformly drawn to the vacuum chamber, protruding approximately 1-2 mm from the adjoining skin surface. The maximum protrusion of the drawn skin from the adjoining skin surface is limited by a clear transmitting element defining the proximate end of the vacuum chamber. The clear transmitting element is separated from the adjoining skin surface by a gap of preferably 2 mm, and ranging from 0.5-50 mm. In one embodiment of the invention, the drawn skin abuts the clear transmitting element.

[0081] As referred to herein, "vacuum modulation" means adjustment of the vacuum level within, or of the frequency by which vacuum is applied to, the vacuum chamber. By properly modulating the vacuum, the blood flow rate, in a direction towards the vacuum chamber, within blood vessels at a predetermined depth below the skin surface can be controlled. As the concentration of blood and/or blood vessels is increased within the skin target, the number of light absorbing chromophores is correspondingly increased at the predetermined depth. The value of optical energy absorbance at the predetermined depth, which directly influences the efficacy of the treatment for skin disorders, is therefore increased.

[0082] Preferably-

- a) The wavelength of the light ranges from 400 to 1800 nm.
- b) The pulse duration of the light ranges from 10 nanoseconds to 900 msec.
- c) The energy density of the light ranges from 2 to 150 J/ cm².
- d) The ratio of the maximum length to maximum width of the aperture formed on the distal end of the vacuum chamber ranges from approximately 1 to 4.
- e) The level of the applied vacuum within the vacuum chamber ranges from 0 to 1 atmosphere.
- f) The frequency of vacuum modulation ranges from 0.2 to 100 Hz.
- g) The light is fired after a predetermined delay following application of the vacuum.
- h) The predetermined delay ranges from approximately 10 msec to approximately 1 second.
- i) The duration of vacuum application to the vacuum chamber is less than 2 seconds.
- j) Vacuum modulation is electronically controlled.

[0083] In one embodiment of the invention, the means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target is at least one support element positioned at a skin area adjoining the skin target and having a thickness suitable for inducing an increase in the concentration of blood and/or blood vessels within said predetermined depth. The apparatus may further comprise at least one leg having a thickness considerably less than the at least one support element and positioned at the periphery of the vacuum chamber, said at least one leg being separated from an adjacent support element, the at least one support

element being adapted to urge blood expelled by said at least one leg towards the skin target.

[0084] The predetermined depth under the skin surface at which optical energy is absorbed is selected in order to thermally injure or treat predetermined skin structures located at said depth.

[0085] Due to implementation of the apparatus, the treatment energy density level for various types of treatment is significantly reduced, on the average of 50% with respect with that associated with prior art devices. The treatment energy density level is defined herein as the minimum energy density level which creates a desired change in the skin structure, such as coagulation of a blood vessel, denaturation of a collagen bundle, destruction of cells in a gland, destruction of cells in a hair follicle, destruction of unwanted lesions by means of photodynamic therapy, or any other desired effects. The following is the treatment energy density level for various types of treatment performed with use of the present invention:

a) treatment of vascular lesions, port wine stains, telangiectasia, rosacea, and spider veins with light emitted from a dye laser unit and having a wavelength of 585 nm: 5-12 J/cm²;

b) treatment of vascular lesions, port wine stains, telangiectasia, rosacea, and spider veins with light emitted from a diode laser unit and having a wavelength of 940 nm: 10-30 J/cm²;

c) treatment of vascular lesions with light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570-900 nm: 5-20 J/cm²;

d) photorejuvenation with light emitted from a dye laser unit and having a wavelength of 585 nm: 1-4 J/cm²;

e) photorejuvenation with light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570-900 nm: 5-20 J/cm²;

f) photorejuvenation with a combined effect of light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570-900 nm and of a RF source: 10 J/cm² for both the intense pulsed non-coherent light unit and RF source;

g) hair removal with light emitted from a Nd:YAG laser unit and having a wavelength of 1604 nm: 25-35 J/cm²; and

h) Porphyrin-based photodynamic therapy with light emitting diodes delivering blue light (420 nm), orange light (585 nm), or red light (630 nm): 5-20 J/cm².

[0086] The preferably further comprises a control unit for controlling operation of the vacuum applying means and light source. The control unit is also suitable for controlling operation of at least one control valve in communication with the vacuum chamber, for firing the light after a predetermined delay following application of the vacuum, and for electronically modulating the vacuum.

[0087] In one aspect, the apparatus further comprises a skin contact detector for sensing the placement of the vacuum chamber onto the skin target, the control unit being suitable for activating the vacuum applying means in response to a signal transmitted by said skin contact detector.

[0088] In one aspect, the apparatus further comprises a light detector for sensing the termination of the light directed to the skin target, the control unit being suitable for regulating a control valve in response to a signal transmitted by said light detector so as to introduce atmospheric pressure air to the interior of the vacuum chamber.

[0089] In one aspect, the apparatus further comprises a pulsed radio frequency (RF) source for directing suitable electromagnetic waves to the skin target. The frequency of the electromagnetic waves ranges from 0.2-10 MHz. The RF source is either a bipolar RF generator which generates alternating voltage applied to the skin surface via wires and electrodes or a monopolar RF generator with a separate ground electrode. The control unit is suitable for transmitting a first command pulse to the at least one control valve and a second command pulse to both the intense pulsed light source and RF source.

[0090] In one aspect, the apparatus further comprises an erythema sensor, said sensor suitable for measuring the degree of skin redness induced by the vacuum applying means. The control unit is suitable for controlling, prior to firing the light source, the energy density of the light emitted from the light source, in response to the output of the erythema sensor.

[0091] In one aspect, the vacuum chamber has a proximate cover formed with an aperture, said cover being attachable to a handpiece, such as a light guide, having an integral clear transmitting element.

[0092] In one aspect, the apparatus further comprises means for skin cooling, said skin cooling means adapted to reduce the rate of temperature increase of the epidermis at the skin target.

[0093] In one aspect, the apparatus further comprises means for preventing passage of skin cooling gel to the vacuum applying means.

[0094] In another embodiment of the invention, the apparatus is suitable for alleviating or preventing pain caused by a non-ablative light-based treatment of a targeted skin structure. Accordingly, the gap separating said the clear transmitting element from the skin surface adjoining said the skin target and the magnitude of the proximally directed force resulting from said the applied vacuum in combination are suitable for drawing said the skin target to said the vacuum chamber via the opening on the distal end of the vacuum chamber said aperture until said the skin target contacts said

the clear transmitting element; and the control means is suitable for firing the light source after the first predetermined delay, following operation of the vacuum applying means.

[0095] In one aspect, the apparatus is suitable for causing the skin target to contact the clear transmitting element for a duration equal to the first predetermined delay, whereby pain signals generated by the nervous system during the treatment of the skin structure are alleviated or prevented.

[0096] The control means is preferably suitable for controlling the vacuum level generated by the vacuum applying means, and has a plurality of finger depressable buttons, each of which being adapted to set the vacuum applying means and light source at a unique combination of operating conditions so as to generate a predetermined vacuum level within the vacuum chamber and to fire the light source after a predetermined time delay following the operation of the vacuum applying means.

[0097] In one aspect, a single light source and vacuum pump are operable in conjunction with differently configured vacuum chambers, for example a vacuum chamber that is suitable for pain alleviation or a vacuum chamber that is suitable for inducing an increase in blood concentration within a skin target. Each differently configured vacuum chamber is releasably attachable to a treatment light handpiece, e.g. by means of suitable threading or clips.

Brief Description of the Drawings

[0098] In the drawings:

- Fig. 1 is a schematic drawing which illustrates the propagation of an intense pulsed laser beam from a handpiece to a skin target according to a prior art method;
- Fig. 2 is a schematic drawing which illustrates the propagation of an intense pulsed non-coherent light beam from a handpiece to a skin target according to a prior art method;
- Fig. 3 is a schematic drawing of a prior art treatment method by which pressure is applied to a skin target, in order to expel blood from those portions of blood vessels which are in the optical path of subcutaneously scattered light;
- Fig. 4 is a schematic drawing of a prior art vacuum-assisted rolling cellulite massage device;
- Fig. 5 is a schematic drawing of a prior art vacuum-assisted hair removal device adapted to reduce the blood concentration within a skin fold formed thereby, in order to illuminate two opposed sides of the skin fold and consequently remove melanin-rich hair shafts;
- Fig. 6 is a schematic drawing of apparatus in accordance with one embodiment of the present invention, employing a manually occluded U-shaped evacuation chamber;
- Fig. 7 is a schematic drawing of apparatus in accordance with another embodiment of the present invention, employing an electronically controlled evacuation chamber;
- Fig. 8 is a schematic drawing of apparatus in accordance with the present invention, employing an intense pulsed non-coherent light source;
- Fig. 9 is a schematic drawing of apparatus in accordance with the present invention, which is provided with a skin chiller;
- Fig. 10 is a drawing which schematically illustrates the effect of applying a subatmospheric pressure to a vacuum chamber in order to increase the blood concentration in skin drawn towards the vacuum chamber;
- Fig. 11 is a drawing which schematically illustrates the increased concentration of a plurality of blood vessels in a skin target following application of a vacuum to a vacuum chamber, resulting in increased redness of skin and enhanced absorption of light;
- Fig. 12 is a photograph illustrating the change in skin color following treatment of a fine wrinkle by use of a vacuum assisted handpiece in accordance with the present invention;
- Fig. 13 is a schematic drawing of another embodiment of the invention, illustrating propagation of intense pulsed light from an external light source to a transparent modulated vacuum chamber;
- Fig. 14 schematically illustrates another embodiment of the invention which employs both an intense pulsed light source and a radio frequency source, for improved coagulation of blood vessels;
- Figs. 15a and 15b schematically illustrate a vacuum chamber which is attachable to a light guide, wherein Fig. 15a illustrates the vacuum chamber prior to attachment and Fig. 15b illustrates the vacuum chamber following attachment;
- Fig. 16 is a schematic drawing of apparatus in accordance with another embodiment of the invention, which is suitable for alleviating pain during a light-based skin treatment;
- Fig. 17 is a schematic drawing of an exemplary trap, for preventing the passage of gel to a vacuum pump;
- Fig. 18 is a schematic perspective drawing of apparatus in accordance with another embodiment of the invention, illustrating a detachable upper portion of a vacuum chamber;
- Fig. 19 is a schematic drawing of an exemplary skin cooling device, which is suitable for the apparatus of Fig. 16;
- Fig. 20 is a schematic drawing of apparatus in accordance with yet another embodiment of the invention;
- Fig. 21 is a photograph of the back of a patient, illustrating the efficacy of the hair removal treatment of the invention;

- Fig. 22 schematically illustrates a vacuum chamber which is configured to induce the expulsion of blood from a skin target to a peripheral skin area;
- Fig. 23 schematically illustrates a vacuum chamber which is configured to induce blood transfer from a peripheral skin area to a skin target;
- 5 - Figs. 24A and 24B schematically illustrate the accumulation of gel as a vacuum chamber is displaced from skin area to another;
- Fig. 25 schematically illustrates a vacuum chamber to which a vacuum is applied by means of a peristaltic pump;
- Fig. 26A is a plan view of an array of vacuum chambers and Fig. 26B is a cross sectional view thereof, taken about plane A-A of Fig. 26A;
- 10 - Figs. 27A-C illustrate the production of a vacuum chamber by a vertically displaceable cover in three stages; and
- Fig. 28 is a schematic perspective view of a sapphire transmitting element that is suitable for transmitting both light and RF waves to a skin target.

Detailed Description of Preferred Embodiments

15 **[0099]** The present invention is directed to apparatus which is provided with a unit for evacuating vapors, such as condensed vapors that were produced during the chilling of skin prior to the firing of the laser unit. The evacuation unit comprises a U-shaped vacuum chamber through which monochromatic or intense pulsed light passes as it is directed to a skin target, and a vacuum pump. During operation of the vacuum pump, the vacuum level within the vacuum chamber

20 is increased by occluding a conduit of the vacuum chamber e.g. by a finger of the operator. As vacuum is applied to the skin target, skin is drawn toward the vacuum chamber and the concentration of blood vessels in the vicinity of the target increases. The added concentration of blood vessels increases the absorption of light within the tissue, and therefore facilitates treatment of a skin disorder.

25 **[0100]** Fig. 1 illustrates the propagation of an intense pulsed laser beam the wavelength of which is in the visible or near infrared region of the spectrum, i.e. shorter than 1800 nm, from the distal end of a handpiece to a skin target according to a prior art method. Handpiece 1001 comprises clear transmitting element 1002, such as a lens or a window, which transmits monochromatic beam 1007 emitted from the laser unit and impinges skin target 1004. The beam penetrates skin target 1004 and selectively impinges a subcutaneous skin structure to be thermally injured, such as collagen bundle 1005, blood vessel 1009, or hair follicle 1006. In this method, external pressure or vacuum is not applied to the skin.

30 **[0101]** Fig. 2 illustrates a prior art non-coherent intense pulsed light system from which light is fired to a skin target for e.g. treatment of vascular lesions, hair removal, or photorejuvenation. Handpiece 1010 comprises light guide 1011 which is in contact with skin target 1004. Beam 1012, which is generated by lamp 1013 and reflected from reflector 1014, is non-coherent and further reflected by the light guide walls. In some handpieces, such as those produced by Deka (Italy), a clear transmitting element is utilized, rather than a light guide. Chilling gel is often applied to the skin when such

35 a light system is employed. In this method, external pressure or vacuum is not applied to the skin, and the handpiece is gently placed on the skin target, so as to avoid removal of the gel layer, the thickness of which is desired to remain at approximately 0.5 mm.

40 **[0102]** Fig. 3 illustrates a prior art laser system similar to those of US Patent Nos. 5,595,568 and 5,735,844, which employs an optical component 1022 at the distal end thereof in contact with skin target 1004. Pressure is applied to skin target 1004, in order to expel blood from those portions of blood vessels 1025, as schematically illustrated by the arrows, which are in the optical path of subcutaneously scattered light, thereby allowing more monochromatic light to impinge hair follicle 1006 or collagen bundle 1005. Concerning hair removal, melanin is generally utilized as an absorbing chromophore.

45 **[0103]** Fig. 4 illustrates a prior art device 1031, such as that produced by LPG (France), which is in pressing contact with skin 1033 in order to perform a deep massage of cellulite adipose layer 1037. Device 1031 is formed with a convex surface 1039 in a central region of its planar skin contacting surface 1043. Device 1031 stimulates the flow of lymphatic fluids in their natural flow direction 1038 in order to remove toxic materials from the adjoining tissue. The stimulation of lymphatic fluid flow is achieved by applying a vacuum to the interior of device 1031 so that air is sucked therefrom in the direction of arrow 1034 of the skin. The application of the vacuum draws skin toward convex surface 1039 and induces

50 the temporary formation of skin fold 1040, which is raised in respect to adjoining skin 1033. Due to the elasticity of skin, skin fold 1040 returns to its original configuration, similar to the adjoining skin, upon subsequent movement of device 1031, while another skin fold is formed. As device 1031 is moved by hand 1036 of a masseur in direction 1044 of the device, similar to natural flow direction 1038, the lymphatic fluids flow in their natural flow direction. However, the lymphatic fluids will not flow if device 1031 were moved in a direction opposite to direction 1044. Wheels 1035 enable constant

55 movement of device 1031.

[0104] In some cellulite massage devices, such as those produced by Deka (Italy) or the Lumicell Touch (USA), a low power continuous working infrared light source with a power level of 0.1- 2 W/cm² provides deep heating of the cellulite area and additional stimulation of lymphatic flow. Such a light source is incapable of varying the temperature by more

than 2-3 °C, since higher temperatures would be injurious to the tissue and cause hyperthermia. Consequently these massage devices are unable to attain the temperatures necessary for achieving selective thermal injury of blood vessels, hair follicles or for the smoothening of fine wrinkles. Due to the movement of the device, the amount of optical energy, e.g. by means of an optical meter, to be applied to the skin cannot be accurately determined.

[0105] Fig. 5 illustrates a prior art hair removal device, similar to the device of US Patent No. 5,735,844, which is provided with a slot 1052 within a central region of skin contacting surface 1051 of handpiece 1050. When handpiece 1050 is placed on skin surface 1058 and a vacuum is applied to the handpiece via opening 1053, skin fold 1054 is formed. A narrow slot 1052 induces formation of a correspondingly longer skin fold 1054. Optical radiation is transmitted to the two opposed sides 1056 of skin fold 1054 by a corresponding optical fiber 1055 and optical element 1057. Upon application of the vacuum, skin fold 1054 is squeezed to prevent blood flow therethrough. This device is therefore intended to reduce the concentration of blood within skin fold 1054, in order to increase illumination of melanin-rich hair shafts, in contrast with the apparatus of one embodiment of this invention by which blood concentration is increased within the slight vacuum-induced skin protrusion so as to induce increased light absorption, as will be described hereinafter. Furthermore, this prior art device, due to the reduced concentration of blood within skin fold 1054, is not suitable for treatment of vascular lesions, photorejuvenation, or the method of hair removal which is aided by the absorption of optical energy by blood vessels that surround or underly hair follicles (as opposed to the method of hair removal which is aided by the absorption of optical energy by melanin).

[0106] Although the application of a vacuum to a skin surface has been employed in the prior art to supplement skin treatments performed by means of optical energy, many significant differences between prior art apparatus for a vacuum-assisted light-based skin treatment to that of the present invention are evident:

a) The prior art application of vacuum is intended to remove smoke or vapors caused by the light-based ablation of a skin surface. By the apparatus of the present invention, in contrast, the optical energy does not interact with the skin surface, but rather is targeted to subcutaneous skin structures without producing smoke or vapors.

b) In order to remove smoke and vapors produced by a prior art light-based skin treatment, a flushing process is required whereby the produced smoke and vapors are purged and replaced by clean air. A low vacuum level is therefore generated, since if a high level vacuum were generated, the treatment handpiece would be prevented from being lifted and displaced from one skin target to another. In contrast, a high vacuum level of approximately 0 atmospheres is generated in the method of the present invention to sufficiently draw the skin into the vacuum chamber and to therefore facilitate the treatment of a skin disorder, yet the treatment handpiece may be quickly repositioned from one skin target to another.

c) Since smoke or vapor removal by means of prior art apparatus prevents the same from adhering to the distal window of a light source, the vacuum application by prior art apparatus should immediately follow each light treatment pulse. The apparatus of one embodiment of the present invention, in contrast, stimulates an increase in blood vessel concentration by applying the vacuum in order to increase light absorption, and therefore the vacuum needs to be applied prior to the firing of the treatment beam.

d) Prior art apparatus does not provide means to temporarily modulate the vacuum level. In contrast, the apparatus of the present invention has control means for modulating the applied vacuum level, by which the optical absorptivity of a skin target may be adjusted in order to effect a desired treatment.

e) Evacuation of skin ablation and of smoke or debris by means of prior art apparatus precludes employment of a protective gel layer over the skin, since the gel forms a barrier between the skin surface and the ambient air. Even if a prior art apparatus were conducive to the application of gel, no provision is made to prevent obstruction of the vacuum pump. In contrast, the apparatus of the present invention allows for the application of gel to the skin prior to a vacuum-assisted non-ablative treatment, since the light-based treatment is subcutaneous, and furthermore, provides means for preventing the obstruction of the vacuum pump.

f) With respect to apparatus of the prior art which is intended to induce blood expulsion from local skin tissue, the treatment beam is limited, to a laser beam of approximately 5 mm. If the treatment beam were significantly larger, e.g. 40 mm, blood expulsion would not be uniform and instantaneous, and therefore blood may remain in the skin tissue after a laser beam has been fired. In contrast, the apparatus of the present invention is suitable for performing skin treatments when the treatment beam is 40 mm, and furthermore is suitable for performing skin treatments by means of an IPL unit having a beam diameter which is significantly larger than that of a laser unit.

g) Prior art vacuum-assisted light-based skin treatment devices are known only to reduce the concentration of blood within a skin target, in order to increase the exposure of the skin target to the treatment light. The apparatus of the present invention, however, employs a vacuum chamber overlying the skin target, as will be described hereinafter, which does not necessarily expel blood from the epidermis of the skin target, but rather increases the blood volume fraction within the skin target.

[0107] Figs. 22 and 23 illustrate two vacuum chamber configurations, respectively, which induce different blood transfer

effects. In Fig. 22, vacuum chamber 100 is configured to induce the expulsion of blood 140 from skin target 130 to peripheral skin area 135, as indicated by the direction of the arrows, while vacuum chamber 200 of Fig. 23 is configured to induce blood transfer from peripheral skin area 210 to skin target 230, as indicated by the direction of the arrows.

[0108] The direction of blood transfer is dependent on the ratio of the skin target diameter to the thickness of the vacuum chamber walls. In Fig. 22, vacuum chamber 100 has thin walls 105 which serve to squeeze blood while peripheral skin area 135 slides under walls 105 as skin target 130 is drawn proximally. As walls 105 are thinner or sharper, the localized pressure under the walls is increased, resulting in a more effective squeezing of blood in the same direction as the skin sliding direction and outwardly from walls 105. On the other hand, as shown in Fig. 23, relatively thick support elements 250 of vacuum chamber 200 induce blood transfer towards skin target 230. Due to the increased thickness of support elements 250, the frictional force applied by support elements 250 onto the underlying skin surface is increased relative to that applied by walls 105 of Fig. 22, and therefore peripheral skin area 210 is prevented from sliding under support elements 250. As support elements 250 press on the underlying skin surface, albeit by a localized pressure less than applied by walls 105 of Fig. 22, the corresponding blood vessels are squeezed and blood is forced to flow towards skin target 230.

[0109] Fig. 6 illustrates the apparatus according to an embodiment of the invention, which is generally designated by numeral 1070. Apparatus 1070 comprises light source 1071, handpiece 1073 provided with clear transmitting element 1076 at its distal end, an evacuation unit which is designated by numeral 1090, and preferably a pressure indicator (not shown) for indicating the pressure within the vacuum chamber.

[0110] Evacuation unit 1090 comprises vacuum pump 1080, vacuum chamber C, and conduits 1078 and 1079 in communication with chamber C. Vacuum chamber C, which is placed on skin surface 1075, is formed with an aperture (not shown) on its distal end and is provided with a clear transmitting element 1076 on its proximate end. Vacuum chamber C is integrally formed with handpiece 1073, such that cylindrical wall 1091 is common to both handpiece 1074 and vacuum chamber C. Element 1076 is transparent to beam 1074 of intense pulsed monochromatic or non-coherent light which is directed to skin target T. Element 1076 is positioned such that beam 1074 is transmitted in a direction substantially normal to skin surface 1075 adjoining skin target T. The ratio of the maximum length to maximum width of the aperture, which may be square, rectangular, circular, or any other desired shape, ranges from approximately 1 to 4. Since the aperture is formed with such a ratio, skin target T is proximately drawn, e.g. 1 mm from skin surface 1075, and is slightly deformed, as indicated by numeral 1087, while increasing the concentration of blood in skin target T. Likewise, employment of an aperture with such a ratio precludes formation of a vacuum-induced skin fold, which has been achieved heretofore in the prior art and which would reduce the concentration of blood in skin target T.

[0111] Wall 1091 is formed with openings 1077 and 1084 in communication with conduits 1078 and 1079, respectively. The two conduits have a horizontal portion adjacent to the corresponding opening, a vertical portion, and a long discharge portion. Openings 1077 and 1084 are sealed with a corresponding sealing element 1093, to prevent seepage of fluid from the vacuum chamber. Conduit 1079 is also in communication with vacuum pump 1080, which draws fluid, e.g. air, thereto at subatmospheric pressures. U-shaped vacuum chamber C is therefore defined by clear transmitting element 1076 of the handpiece, slightly deformed skin surface 1087, wall 1091 and conduits 1078 and 1079.

[0112] A suitable light source is a pulsed dye laser unit, e.g. produced by Candela or Cynosure, for the treatment of vascular lesions, which emits light having a wavelength of approximately 585 nm, a pulse duration of approximately 0.5 microseconds and an energy density level of 10 J/cm². Similarly any other suitable high intensity pulsed laser unit, such as a Nd:YAG, pulsed diode, Alexandrite, Ruby or frequency doubled laser, operating in the visible or near infrared region of the spectrum may be employed. Similarly, a laser unit generating trains of pulses, such as the Cynosure Alexandrite laser, the Lumenis "Quatim" IPL or Deka "Silkapiil". The emitted light is transmitted via optical fiber 1072 to handpiece 1073. Handpiece 1073 is positioned such that clear transmitting element 1076 faces skin surface 1087. Beam 1074 propagating towards slightly protruded skin surface 1087 is substantially normal to skin surface 1075.

[0113] Following operation of vacuum pump 1080, air begins to become evacuated from vacuum chamber C via conduit 1079. Occluding conduit 1078, such as by placing finger 1083 of an operator on its outer opening increases the level of the vacuum within chamber C to a pressure ranging from 200 to 1000 millibar. The application of such a vacuum slightly draws skin target T towards chamber C without being pressed, as has been practiced heretofore in the prior art, thereby increased the concentration of blood vessels within skin target T. The efficacy of a laser unit in terms of treatment of vascular lesions is generally greater than that of the prior art, due to the larger concentration of blood vessels in skin target T, resulting in greater absorption of the optical energy of beam 1074 within bodily tissue.

[0114] The operator may fire the laser following application of the vacuum and the subsequent change in color of skin target T to a reddish hue, which indicates that the skin is rich in blood vessels. The time delay between the application of the vacuum and the firing of the laser is based on clinical experience or on visual inspection of the tissue color.

[0115] Fig. 7 illustrates another embodiment of the present invention wherein the operation of the vacuum pump and of the pulsed laser or non-coherent light source is electronically controlled. The depth of light penetration within the tissue may be controlled by controlling the time delay between application of the vacuum and the firing of the pulsed light. If the time delay is relatively short, e.g. 10 msec, blood vessel enrichment will occur only close to the surface of

the skin at a depth of approximately 0.2 mm, while if the delay is approximately 300 msec, the blood vessel enrichment depth may be as great as 0.5-1.0 mm.

[0116] Apparatus 1170 comprises handpiece 1101, laser system 1116, evacuation unit 1190 and control unit 1119.

[0117] Laser system 1116 includes a power supply (not shown), a light generation unit (not shown), and power or energy detector 1130 for verifying that the predetermined energy density value is applied to the skin target. Handpiece 1101 held by the hand of the operator is provided with lens 1104, which directs monochromatic beam 1105 transmitted by optical fiber 1103 from laser system 1116 to skin target area 1140. Clear transmitting element 1100 defining vacuum chamber 1106 is generally in close proximity to skin surface 1142, at a typical separation H of 1-2 mm and ranging from 0.5 to 4 mm, depending on the diameter of the handpiece. The separation is sufficiently large to allow for the generation of a vacuum within chamber 1106, but less than approximately one-half the diameter of the window 1100, in order to limit the protrusion of skin target 1140 from the adjoining skin surface 1142. By limiting the separation of element 1100 from skin surface 1142 while maintaining the vacuum applied to skin target 1140, formation of a skin fold is precluded while more blood may be accumulated in a smaller skin thickness. Therefore a significant local rise in the temperature of a blood vessel, which ranges from 50-70°C, is made possible.

[0118] Evacuation unit 1190 comprises vacuum chamber 1106 which is not U-shaped, miniature vacuum pump 1109 suitable for producing a vacuum ranging from 200-1000 millibar, conduit 1107 and control valve 1111 through which subatmospheric fluid is discharged from chamber 1106, and miniature pressurized tank 1110 containing, e.g. 100 ml, which delivers air through conduit 1112 and control valve 1108 to chamber 1106. If so desired, a clear transmitting element need not be used, and vacuum chamber 1106 defined by lens 1104 will have an accordingly larger volume.

[0119] Control unit 1119 comprises the following essential elements:

- a) Display 1115 of the energy density level of the monochromatic light emitted by laser system 1116 and a selector for selecting a predetermined energy density.
- b) Confirmation indicator 1120 which verifies that the selected energy density is being applied to the skin. Control circuitry deactivates the laser power supply if a beam having an energy density significantly larger than the predetermined value is being fired.
- c) Display 1122 concerning the pulse structure, such as wavelength, pulse duration and number of pulses in a train.
- d) Control circuitry 1123 for selecting the time delay between operation of vacuum pump 1109 and laser system 1116.
- e) Selector 1124 for controlling the vacuum level in vacuum chamber 1106 by means of pump 1109.
- f) Control circuitry 1126 for controlling the vacuum duty cycle by regulating the operating cycle of vacuum pump 1109, the open and close time of control valve 1111, the average vacuum pressure, the vacuum modulation frequency, and the repetition rate.
- g) Control circuitry 1143 for delivering fluid from positive pressure tank 1110 by controlling the duty cycle of control valve 1108.
- h) Light detector 1185 for sensing whether light is impinging onto skin target 1140.

[0120] Tank 1110, in which air having a pressure ranging from 1-2 atmospheres is contained, provides a fast delivery of less than 1 msec of air into chamber 1106, as well as a correspondingly fast regulation of the vacuum level therein by first opening control valves 1108 and 1111 and activating vacuum pump 1109. After a sufficient volume of fluid, e.g. 1 ml, is delivered to chamber 1106, control valve 1108 is closed. Control circuitry 1126 and 1143 then regulate the operation of the control valves so to maintain a predetermined level of vacuum. Upon achieving the predetermined vacuum level, control circuitry 1123 fires laser system 1116 after the predetermined time delay, which may range from 1-1000 msec.

[0121] Control unit 1119 may also be adapted to increase the pressure in vacuum chamber 1106 to atmospheric pressure (hereinafter in "a vacuum release mode") following deactivation of the pulsed light beam source, to allow for effortless repositioning of the vacuum chamber to another skin target. In order to achieve a fast response time between the deactivation of the light source and the pressure increase within the vacuum chamber prior to repositioning the vacuum chamber to another skin target, light detector 1185 is employed to detect the light emitted by the treatment light source. When the light detector ceases to detect light emitted by the light source, a suitable command is transmitted to control unit 1119, whereupon the latter generates a command to open control valve 1111, in order to increase the vacuum chamber pressure. Alternatively, the vacuum within the vacuum chamber may be released by depressing a pneumatically or electrically actuated button located on the handpiece, following deactivation of the light source. Employment of a light detector which triggers the release of the vacuum in the vacuum chamber in order to allow for the speedy repositioning of the treatment handpiece has particular significance in conjunction with fast treatment systems such as the hair removal "Light Sheer" diode system produced by Lumenis, which operates at a fast rate of 1 pulse per second.

[0122] Fig. 8 illustrates apparatus 1270, which comprises a non-coherent intense pulsed light system similar to that described with respect to Fig. 2 and provided with Xe flashlamp 1201, such as one manufactured by Lumenis, Deka, Palomar, or Syneron. Reflector 1202 reflects the emitted light 1207 to light guide 1208. Distal end 1203 of light guide

1208 is separated 1-2 mm from skin surface 1242 to allow for the generation of a vacuum in vacuum chamber 1206 without compromising treatment efficacy by limiting the protrusion of the skin target from the adjoining skin surface 1242.

[0123] Figs. 15a-b illustrate another embodiment of the invention wherein apparatus 1670 comprises a vacuum chamber 1601 which is attached to intense pulsed light guide 1602. Fig. 15a schematically illustrates vacuum chamber 1601 prior to attachment to the light guide, and Fig. 15b schematically illustrates the attachment of vacuum chamber 1601 to light guide 1602. Vacuum chamber 1601 has walls 1608, side openings 1605 formed in walls 1608, and proximate cover 1612 formed with a proximate aperture 1607 having dimensions substantially equal to the cross section of light guide 1602. Attachment means 1604 facilitates the attachment of vacuum chamber 1601 to light guide 1602 or to any element adapted to protect the light guide. Attachment means 1604 preferably also seals the interface between cover 1612 and light guide 1602, to prevent the infiltration of air into vacuum chamber 1601 after the generation of a vacuum therein. Clear transmitting element 1625 of light guide 1602 also serves to prevent an increase in vacuum chamber pressure. Once vacuum chamber 1601 is attached to light guide 1602, the vacuum chamber may be placed on a selected skin surface 1603. After a vacuum is generated within chamber 1601, skin target 1606 is drawn into the interior of vacuum chamber 1601, whereupon pulsed light beam 1620 may be fired towards skin target 1606. Vacuum chamber 1601 may be advantageously attached to the distal end of any existing IPL or laser source, to convert the light source into an apparatus for enhancing the absorption of light in targeted skin structures, in accordance with the present invention. This embodiment is particularly useful when the distal end of the light source is provided with an integral skin chilling device.

[0124] Fig. 9 illustrates the placement of apparatus 1370 onto arm 1310. Apparatus 1370 comprises handpiece 1301, evacuation unit 1390, and skin chiller 1300 for cooling the epidermis of arm 1310, which is heated as a result of the impingement of monochromatic light thereon. Skin chiller 1300 is preferably a metallic plate made of aluminum, which is in contact with the epidermis and cooled by a thermoelectric cooler. The temperature of the plate is maintained at a controlled temperature, e.g. 0°C. The chilled plate is placed on a skin region adjacent to skin target 1340. The epidermis may be chilled prior to the light treatment by other suitable means, such as by the application of a gel or a low temperature liquid or gas sprayed onto the skin target.

[0125] It will be appreciated that the utilization of a U-shaped vacuum chamber 1306 for the evacuation of vapors which condense on clear transmitting element 1376 is particularly advantageous when a skin chiller in permanent contact with the handpiece outer wall is employed. Such a skin chiller results in condensation of vapors on the transmitting element that would not be evacuated without employment of an evacuation unit in accordance with the present invention. Alternatively, the skin chiller may be releasably attached to the vacuum chamber.

[0126] Fig. 10 schematically illustrates the effect of applying a subatmospheric pressure to a skin target, in accordance with the present invention, in order to enhance the absorption of light by blood vessels within the skin target. For clarity, the drawing illustrates the effect with respect to a single blood vessel; however, it should be appreciated that many blood vessels contribute to the effect of increased blood transport whereby a plurality of blood vessels are drawn to the epidermis, resulting in increased absorption of the optical energy. The protrusion of the skin target relative to the adjoining skin surface is also shown in disproportionate fashion for illustrative purposes.

[0127] The increase in light absorption within blood vessels due to the application of a vacuum in the vicinity of a skin target depends on the vacuum level, or the rate of vacuum modulation, and the skin elasticity which is reduced with increased age. As shown, blood vessel 1329 of diameter D is in an underlying position relative to vacuum chamber 1326. By applying a vacuum by means of evacuation unit 1390, blood flow is established in blood vessel 1329 in the direction of arrow M, due to a difference of pressures between points A and B closer and farther from vacuum chamber 1326, respectively. If the blood vessel is a vein, the flow will be established in only one direction, due to the influence of the corresponding vein valve.

[0128] According to the Hagen-Poiseuille equation concerning the flow of viscous fluids in tubes, the discharge from a tube and consequently the duration of flow therethrough depends on a pressure gradient along the tube, the fourth power of the diameter of the tube, and the length thereof. For example, diameters of 100 microns are common for capillaries adjacent to the papillary dermis at a depth of approximately 200 microns and 500-micron blood vessel diameters can be found in the hair bulb at a depth of 3 mm. A typical blood vessel length is approximately 1-2 cm. It will be appreciated that although the blood vessel diameters generally increase with depth, the pressure gradient along the blood vessel is smaller at deeper layers of the skin. As a result, for a given pressure, such as the application of a zero millibar vacuum, each depth from the skin surface corresponds to a characteristic time response for being filled by blood. As a result, modulation of the vacuum by opening and closing control valve 1111 (Fig. 7) controls the flow of blood through blood vessels and consequently controls the degree of light absorption by a blood vessel at a given depth from skin surface 1342. In a realistic situation wherein a plurality of blood vessels are located within a skin target, each skin layer is characterized by a different modulation frequency which typically ranges between 100 Hz for upper layers and 1 Hz for the deep layers under the hair follicles. By opening control valves 1108 and 1111 (Fig. 7) by a varying frequency, the operator may modulate the vacuum applied to the skin target and thereby vary the blood richness of different skin layers.

[0129] The operator typically determines an instantaneous modulation frequency of control valves 1108 and 1111 by

visually inspecting the skin target and viewing the degree of redness thereat in response to a previous control valve modulation frequency. In addition to improving the treatment efficacy, an increased degree of redness within the skin target advantageously requires a lower energy density of intense pulsed light for achieving blood coagulation or blood heating resulting in the heating of the surrounding collagen. Alternatively, an erythema, i.e. skin redness, meter, e.g. produced by Courage-Hazaka, Germany, may be employed for determining the degree of redness, in order to establish the necessary energy density for the treatment.

[0130] For example, a modulation frequency as high as 40 Hz or the firing of a Dye laser unit approximately 1/40 seconds after application of a vacuum may be necessary for applications of port wine stains. In contrast, a delay of approximately a half second for fine wrinkle removal and of approximately 1 second for hair removal may be needed for a depth of 1-3 mm under the skin surface.

[0131] Fig. 11 illustrates the concentration of a plurality of blood vessels 1329 in a skin target 1340, which results in the increase of redness of skin and enhanced absorption of light with respect to the hemoglobin absorption spectrum and scattering properties of skin. Light absorption is enhanced by a larger number of blood vessels per unit volume due to the correspondingly larger number of light absorbing chromophores. The beneficial effect of vacuum assisted absorption by Dye lasers or any yellow light, which is strongly absorbed by hemoglobin, is more pronounced on white or yellow skin not rich in blood vessels, such as that of smokers. Such types of skin suffer from enhanced aging and require photorejuvenation, the efficacy of which is improved with the use of the present invention. Enhanced absorption of light is also advantageously achieved when infrared lasers and intense pulsed light sources are employed.

[0132] Fig. 12 is a photograph illustrating the treatment of a fine wrinkle 1401 by means of a vacuum assisted handpiece according to the current invention, which was taken one-half of a second after the application of a vacuum. Circles 1402-4 indicate the sequential treatment spots. The color in the circle 1403 has changed.

[0133] Fig. 23 illustrates another embodiment of the invention, by which blood vessel concentration within a skin target is increased by selecting the thickness of the supporting elements of the vacuum chamber. Vacuum chamber 200 placed on skin target 230 comprises cover 205, clear transmitting element 215 centrally retained within cover 205, relatively thin annular leg 240 having a thickness of T_2 positioned below cover 205 at the outer periphery thereof, relatively thick annular support element 250 of thickness T_1 separated from leg 240 and positioned below cover 205 at skin area 210 adjoining skin target 230, and conduits 255 formed within cover 205 by which the vacuum is applied to the vacuum chamber. Each conduit 255 is provided with an inner inlet 282 and an outer inlet 284. Each inner inlet 282 communicates with volume V_1 interior to annular support element 250 and each outer inlet 284 communicates with volume V_2 , which has a significantly smaller volume than volume V_1 and is formed between support element 250 and surrounding annular leg 240.

[0134] When a vacuum is applied to vacuum chamber 200, the pressure differential between the surrounding ambient air pressure and the generated vacuum within the vacuum chamber urges vacuum chamber 200 to be in pressing relation with the skin adjoining skin target 230. The resultant force associated with the pressure differential acts on both legs 240 and on support elements 250. Since a vacuum is applied onto the two sides of support element 250 via volumes V_1 and V_2 , the resultant force transmitted to underlying skin area 210 by support element 250 produces a substantially uniform squeezing pressure. By virtue of thin vacuum volume V_2 , legs 240 serve as a means to stabilize vacuum chamber 200, which is particularly useful on a skin area that is not completely planar, such as in the vicinity of a bone.

[0135] The wide area pressure applied by support element 250 onto skin area 210 directs the expelled blood towards skin target 230 as well as towards leg 240. Air evacuated from volume V_1 through inner inlets 282 causes skin target 230 to be proximally drawn and blood to be transported from peripheral skin area 210 towards skin target 230. Support element 250 therefore induces inward blood transport from peripheral skin areas 210 to skin target 230, as represented by arrow 272, resulting in a significant increase in the blood volume fraction within skin target 230. After the blood concentration within skin target 230 has sufficiently increased, light beam 260 is suitable for treating vascular lesions with a wavelength well absorbed by the blood vessels within the skin target, and therefore an energy density less than that of the prior art is fired. The depth of light absorption within skin target 230 can be controlled by changing the thickness T of support elements 250.

[0136] Air evacuated from volume V_2 through a corresponding outer inlet 284 causes skin area 290 underlying corresponding volume V_2 to be drawn drawn proximally. Skin area 290 is then pressed by the edge of support element 250 so that blood, as represented by arrow 292, is outwardly transported from support element 250 to leg 240. By inducing outward transport of blood, the blood volume fraction and therefore the depth of light absorption within skin target 230 may be further controlled.

[0137] It will be appreciated that the blood concentration within skin target 230 can be increased solely by the pressure applied by support element 250, without use of legs 240. Likewise, support elements 1325, 1345, and 1502 illustrated in Figs. 10, 11, and 13, respectively, induce blood transport towards the skin target without need of additional legs.

[0138] Fig. 13 illustrates apparatus 1570 which increases blood vessel concentration within a skin target without use of a handpiece. Apparatus 1570 comprises evacuation unit 1590 having a transparent vacuum chamber 1501 and a clear transmitting element 1506, which is made of a thin, transparent polymer such as polycarbonate or of glass, which

is transparent to visible or near infrared light. Vacuum chamber 1501 has a diameter of 5-20 mm and a height of approximately 1-3 mm, in order to avoid excessive protrusion of the skin. Chamber 1501 is preferably cylindrical, although other configurations are also suitable. A soft silicon rim (not shown) is adhesively affixed to the periphery of the chamber 1501, in order to provide good contact with skin surface 1542. Conduit 1503 in communication with control valve 1504 allows for the evacuation of vacuum chamber 1501 by means of a miniature vacuum pump (not shown) and control unit 1505. After chamber 1501 is placed on skin target 1540, pulsed beam 1508 from any existing intense pulsed laser or light source 1509 which operate in the visible or near infrared regions of the spectrum may propagate therethrough and effect treatment of a skin disorder. Vacuum chamber 1501 and conduit 1503 are preferably disposable. When vacuum chamber 1501 is disposable, clear transmitting element 1506 is insertable within a suitable groove formed within the housing of vacuum chamber 1501. Vacuum chamber 1501 may be hand held or may be releasably attachable to the handpiece of light source 1509. When hand held, vacuum chamber 1501, control unit 1505, and a display (not shown) may be integrated into a single device. The treatment may therefore be performed with the use of two hands, one hand, e.g. hand 1530, holding the integrated vacuum chamber device by means of handle 1531 and the other holding the treatment light source. The advantage of this apparatus is its low price and its ability to interact with any intense pulsed laser or non-coherent light source which is already installed in a health clinic.

[0139] The absorption of visible intense pulsed light in blood vessels when vacuum is applied to a skin target may be enhanced by the directing electromagnetic waves to the skin target. Radio frequency waves operating in the range of 0.2-10 Mhz are commonly used to coagulate tiny blood vessels. The alternating electrical field generated by a bipolar RF generator, such as produced by Elman, USA or Synron, Canada, follows the path of least electrical resistance, which corresponds to the direction of blood flow within blood vessels. A monopolar RF may also be employed, such as manufactured by Thermage, USA.

[0140] Fig. 14 illustrates apparatus 1870 which comprises intense pulsed laser or intense pulsed light source 1821, RF source 1811, and evacuation unit 1890. Evacuation unit 1890 comprises vacuum chamber 1801, which is placed on skin surface 1802 to be treated for vascular lesions, miniature vacuum pump 1805, and control valve 1804 for regulating the level of the vacuum in chamber 1801. Clear transmitting element 1806 is positioned in such a way that beam 1820 generated by light source 1821 propagates therethrough and impinges skin surface 1802 at an angle which is substantially normal to the skin surface.

[0141] RF source 1811 is a bipolar RF generator which generates alternating voltage 1807 applied to skin surface 1802 via wires 1808 and electrodes 1809. Alternatively, the RF source is a monopolar RF generator with a separate ground electrode. Electric field 1810 generally follows the shape of blood vessels 1813, which are the best electrical conductors in the skin. Due to the concentration of blood vessels 1813 in the epidermis, the depth of which below skin surface 1802 depending on the vacuum level and the frequency of vacuum modulation, the combined effect of optical energy in terms of beam 1820 and pulsed RF field 1810 heats or coagulates the blood vessels. Control valve 1804 is regulated by means of control unit 1812. A first command pulse 1 of control unit 1812 controls valve 1804 and a second command pulse 2 controls a delayed radio frequency pulse as well as a delayed light source pulse.

[0142] When a vacuum chamber is placed on a skin target, the apparatus provides an additional advantage in terms of the capability of alleviating pain that is normally caused during e.g. the treatment of hair with intense pulsed monochromatic or non-coherent light.

[0143] As shown in Fig. 16, apparatus 1970 is configured so as to bring skin target 1960, when a vacuum is applied, in contact with clear transmitting element 1906, e.g. made from sapphire, which is secured to the proximate end of vacuum chamber 1901. The Applicant has surprisingly discovered that the immediate sharp pain which is normally sensed during a light-based skin treatment is alleviated or eliminated when a skin target contacts the clear transmitting element. The level of the applied vacuum is suitable for drawing skin target 1960 towards vacuum chamber 1901 by a slight protrusion of K, e.g. 2-4 mm, with respect to adjoining skin surface 1965, a distance which is slightly greater than the gap between clear transmitting element 1906 and the distal end of outer wall 1924 of vacuum chamber 1901. During generation of pulsed beam 1908 from any suitable intense pulsed laser or light source propagating through clear transmitting element 1906, whereby hair follicles 1962 located under the epidermis of skin target 1960 are treated by the generated optical energy, skin target 1960 is drawn to be in contact with clear transmitting element 1906. As skin target 1960 is drawn by the vacuum into vacuum chamber 1901 and contacts clear transmitting element 1906 by means of the resulting proximally directed force, the pain signals generated by the nervous system during the heating of hair follicles 1962, or of any other suitable targeted skin structure, of the patient are inhibited. Accordingly, the synchronization of an optimal delay between the application of the vacuum and firing of the light treatment pulse is a key factor in pain reduction, in order to ensure that skin target 1960 is in contact with clear transmitting element 1906 for a sufficiently long nerve inhibiting duration when pulsed beam 1908 is fired. Pain reduction is noticeable with use of this apparatus even when the energy level of the light directed to skin target 1960 is increased, an effect which normally causes an increase in immediate sharp pain.

[0144] Vacuum chamber 100 illustrated in Fig. 22 is also configured to alleviate the pain resulting from the firing of light beam 160 onto skin target 130. When a vacuum is applied onto vacuum chamber 100 via conduits 155, skin target

130 is drawn and contacts clear transmitting element 115. Instead of sensing immediate sharp pain during impingement of each treatment pulse with a skin area 136 of skin target 130, the magnitude of proximally directed force F resulting from the applied vacuum causes nerve 138 surrounding a corresponding hair bulb and extending to skin area 136 to be pressed onto clear transmitting element 115 for a sufficient duration to inhibit the pain sensation. Light beam 160 is of a wavelength which is well absorbed by hair follicles 139. By optimizing the time delay between application of the vacuum and the firing of light beam 160, the pain sensation is sufficiently inhibited and the energy density of light beam 160 need not be decreased.

[0145] The apparatus for alleviating pain during vacuum-assisted light-based treatments of the skin may include a control device (not shown) for adjusting the vacuum level generated by the vacuum pump, as well as the time delay between the application of the vacuum and the firing of light beam. The control device preferably has a plurality of finger depressable buttons, each of which is adapted to set the vacuum pump and light source at a unique combination of operating conditions so as to generate a predetermined vacuum level within vacuum chamber 100 and to result in a predetermined time delay between the operation of the vacuum pump and the firing of light beam 160, and a display to indicate which button was depressed. The apparatus may also comprise control valves in electrical communication with the control device for evacuating air into vacuum chamber during a vacuum applying mode and for introducing air therein during a vacuum release mode, respectively. The health professional is aware of the anticipated pain level that a patient generally senses when one of these buttons is depressed. If the pain threshold of a patient is relatively low or if the application of the vacuum by the vacuum chamber onto the skin target is annoying, the health professional may change the combination of operating conditions by depressing a different button. Alternatively, the pain threshold of a patient may be objectively determined by an electrical measurement of a muscle reflex in response to pain.

[0146] As skin target 130 is pressed onto clear transmitting element 115 during the application of the vacuum, blood is displaced from skin target 130 to peripheral skin area 135. Although the blood fraction volume in peripheral skin area 135 is increased, the latter is nevertheless liable to be damaged by the treatment light, which may diffuse subcutaneously from skin target 130 to skin area 135. To counteract the potential thermal injury to skin area 135, heat absorbing gel (not shown in the figure) is applied to skin target 130 prior to application of the vacuum and is subsequently squeezed to peripheral skin area 135 by means of transmitting element 115. The displaced gel therefore advantageously protects peripheral skin area 135 from being injured by subcutaneously diffused treatment light.

[0147] The apparatus may be advantageously provided with means to prevent the obstruction of the vacuum chamber conduits by heat releasing gel applied to the skin target prior to the treatment. As shown in Figs. 24A and 24B, gel 185 is squeezed to the periphery of vacuum chamber 180 after application of a vacuum. When vacuum chamber 180 is displaced from skin area 190 to skin area 192, further gel is squeezed and accumulates, as shown in Fig. 24B. The gel is eventually aspirated into the vacuum chamber conduits, causing a significant risk of obstruction thereto when a large-diameter treatment beam normally associated with an IPL unit is used and necessitating the employment of a correspondingly large-diameter vacuum chamber. Without employing means to prevent passage of the gel, a large quantity of gel is liable to be drawn through the conduits and to the vacuum pump, eventually resulting in the malfunction of the latter and in less efficacious treatments. Also, aspirated gel tends to contaminate the vacuum chamber, and the cleaning or sterilization of the vacuum chamber prior to the treatment of another patient is difficult.

[0148] Referring back to Fig. 16, vacuum chamber 1901 has two passageways 1930 through which air is evacuated therefrom. Each passageway 1930, which is in fluid communication with the interior of vacuum chamber 1901, is defined by outer wall 1924, vertical portion 1926, and cylindrical horizontal wall 1930 connected to both outer wall 1924 and vertical portion 1926. The distal end of vertical portion 1926 is connected to clear transmitting element 1906, vertically spaced above, and interiorly spaced from, the distal end of outer wall 1924 placed on skin surface 1965, and is connected to vertical portion 1926 of passageway 1930. The top of horizontal passageway wall 1930 is vertically spaced above outer wall 1924, and vacuum chamber 1901 is therefore considered to be U-shaped. Each horizontal wall 1930 terminates with an opening 1917, which is separated from the distal end of outer wall 1924 by P and is laterally separated from centerline 1969 of vacuum chamber 1901 by J. While the gel may be drawn by the applied vacuum or may laterally slide from skin target 1960 after being pressed by clear transmitting element 1906, dimensions P and J are selected so as to ensure that the volume of the passageways 1930 and of the chamber interior between wall 1924 and the adjacent surface of drawn skin target 1960 is sufficiently large to prevent the obstruction of corresponding opening 1917 by gel 1963. For example, a vacuum chamber having a height K of 2 mm, a wall opening diameter of 3 mm, a separation P of 10 mm from the opening to the distal end of the wall, and a lateral separation J of 20 mm from the vacuum chamber centerline to the opening is sufficient to prevent obstruction of the opening by gel.

[0149] Fig. 17 illustrates another arrangement for preventing vacuum pump suction of gel. The arrangement includes trap 1920, conduit 1940 through which gel and air are drawn from the vacuum chamber to trap 1920, and conduit 1945 through which air is drawn from trap 1920 to the vacuum pump, all of which may be disposable. Air evacuated from the vacuum chamber through opening 1917 flow through conduits 1940 and 1945 until introduced to the inlet port of the vacuum pump. The gel which is evacuated from the vacuum chamber collects within trap 1920. Trap 1920 is periodically emptied so that the accumulated gel does not rise above the inlet of conduit 1945. Trap 1920 and conduits 1940 and

1945 are preferably made from a plastic hydrophilic material, to urge the gel to cling to the walls thereof rather than to be drawn thorough the conduits to the vacuum pump. As shown, gel 1966 clings to the walls of conduit 1940 and gel 1967 is collected on the bottom of trap 1920. The conduits may be suitably sized to prevent the passage of gel to the vacuum pump. For example, the diameter of conduit 1940 at the vacuum wall opening is 30 mm and narrows to a diameter of 10 mm at the discharge to trap 1920, and the diameter of conduit 1945 at the inlet side is 5 mm and is 10 mm at the discharge side in the vicinity of the the vacuum pump inlet port.

[0150] Other arrangements for preventing vacuum pump suction of gel may also be employed. For example, the gel may be bound to a suitable ion exchange resin introduced into trap 1920 and thereby be prevented from being drawn through conduit 1945. If so desired, a filter may be provided at the inlet of conduits 1940 and 1945.

[0151] Alternatively, gel may be prevented from exiting the vacuum chamber by increasing the diameter of conduit 1940 at the vacuum wall opening. Consequently, the inwardly directed force acting on the gel which has laterally slid from a drawn skin target by means of the atmospheric air introduced to the vacuum chamber via conduit 1940 during a vacuum release mode is sufficient to prevent the gel from exiting the vacuum chamber. A hydrophobic coating, such as silicon or teflon, may be applied onto the vacuum chamber walls, so that the gel will be prevented from adhering to the vacuum chamber walls, particularly during a vacuum release mode. Instead of adhering to the vacuum chamber walls, the gel falls to the skin surface. Advantageously, gel is therefore not transported to another skin target during the repositioning of the handpiece, but rather assumes the shape of the distal end of the vacuum chamber walls. If the distal end of the vacuum chamber walls is circular, for example, the gel that falls to the skin surface during a vacuum release mode is also circular, indicating to the health professional that is supervising the treatment that the given skin surface has already been impinged by the treatment light.

[0152] In Fig. 18, apparatus 1980 comprises a vacuum chamber having a detachable upper portion, so that the gel retained by the vacuum chamber interior walls may be removed therefrom, such as by dissolving the gel with salt or with any other suitable dissolving agent. Apparatus 1980 comprises upper portion 1983 having an open central area, clear transmitting element 1984 attached to upper portion 1983, vacuum chamber walls 1981, vacuum chamber cover 1982 perpendicular to walls 1981 and suitably sized so as to support upper portion 1983, and a plurality of attachment clips 1987 pivotally connected to a corresponding vacuum chamber wall 1981 for detachably securing upper portion 1983 to vacuum chamber cover 1982. Thin compliant sealing element 1988 is preferably attached to the periphery of vacuum chamber cover 1982, to prevent infiltration of atmospheric air into the vacuum chamber. Conduit 1940 is shown to be in communication with the interior of the vacuum chamber.

[0153] Fig. 25 illustrates another embodiment of apparatus for preventing the obstruction of vacuum chamber conduits by heat releasing gel during vacuum-assisted light-based treatments of the skin. Apparatus 400 comprises vacuum chamber 420, peristaltic pump 430, vacuum controller 440, control valve 450, and micro-switch 460.

[0154] The vacuum applying mode is initiated upon transmission of signal 445 to controller 440, following which peristaltic pump 430 is activated. Peristaltic pump 430 comprises hose 442 connected to conduit 425 in communication with the interior of vacuum chamber 420 and rotatable hub 446, from which a plurality of shoes and/or rollers 448 (referred to hereinafter as "pressing elements") radially extend. As hub 446 rotates, the pressing elements sequentially squeeze a different region of hose 442 and a volume of fluid entrapped by two adjacent pressing elements is thereby forced to flow unidirectionally through hose 442 by a positive displacement action towards end 449 thereof. Consequently, when peristaltic pump 430 is activated, air is drawn from the interior of vacuum chamber 420 to generate a vacuum therein ranging from 0-1 atmospheres. If a considerable amount of gel 405 accumulates within the periphery of vacuum chamber 420, the gel is also forced to flow within hose 442 without causing any obstruction to the latter. The gel that is discharged from end 449 of hose 442 falls onto skin surface 410, indicating that an adjoining skin target 415 has undergone a light-based treatment.

[0155] Micro-switch 460, or any other suitable skin contact detector, is adapted to sense the placement of the handpiece or of vacuum chamber chamber 420, onto skin target 415. Micro-switch 460 generates signal 445 upon sensing the placement of vacuum chamber 420 on skin target 415. Control valve 450 is triggered by a light detector (not shown), which generates signal 455 upon detecting the termination of the light-based treatment pulse 470. Control valve 450 is opened after the generation of signal 455, to introduce atmospheric pressure air 452 to the interior of vacuum chamber 420 via passageway 456 and to thereby initiate the vacuum release mode. Signal 455 is also transmitted to controller 440, to deactivate peristaltic pump 430. The described automatic operation of peristaltic pump 430 therefore prevents the patient from suffering pain during the associated treatment. If so desired, the operation of peristaltic pump 430 may be manually overridden.

[0156] It will be appreciated that a peristaltic pump or a contact detector may be employed in conjunction with any other embodiment of the invention.

[0157] In another embodiment, the vacuum pump is an air pump. When air is evacuated from the vacuum chamber, a piston (not shown) which is normally closed by a spring is opened to allow air to be aspirated. During the vacuum release mode, the piston is set to its original position, returning air to the vacuum chamber and any aspirated gel to the skin surface.

[0158] Figs. 27A-C illustrate another embodiment of the invention wherein a vacuum pump is not needed for vacuum-assisted light-based treatments of the skin. Apparatus 600 comprises a vertically displaceable cover 610 to which clear transmitting element 615 is secured, chamber walls 620 in which vertically displaceable cover 610 is mounted, and sealing element 625 which is secured to the outer periphery of cover 610. Chamber walls 620 surround, and are of a similar shape as, cover 610.

[0159] When cover 610 is in its lowermost position, as shown in Fig. 27A, the cover is flush with skin surface 630 on which is applied a layer of gel 635. In this position, air is prevented from infiltrating between cover 610 and skin target 630, e.g. by means of a sealing element externally affixed to walls 620. When a proximally directed force represented by arrows 652 is applied to cover 610, as shown in Fig. 27B, the cover is raised while sealing element 625 resiliently contacts walls 620. Apparatus 600 is configured such that distal displacement of cover 610 is prevented after having been raised, without application of a subsequent distally directed force. While cover 610 is raised, a vacuum chamber 640 is produced internally to chamber walls 620, due to the increased volume between cover 610 and skin surface 630 while air is prevented from infiltrating therein. The vacuum generated within vacuum chamber 640 as a result of the proximal displacement of cover 610 ranges from 0-1 atmospheres and is suitable for drawing skin target 650 towards the displaced cover 610 as shown, in order to be subsequently impinged by a treatment pulse. When a distally directed force represented by arrows 654 is applied to cover 610 following the light-based treatment, as shown in Fig. 27C, cover 610 returns to its lowermost position in preparation for displacement to the next skin target. Aeration tube 675 in communication with a manually operated or control valve (not shown) may be employed to quicken distal displacement of cover 610 during a vacuum release mode by introducing atmospheric air to vacuum chamber 640 upon conclusion of the skin target treatment.

[0160] Proximally directed force 652 or distally directed force 654 may be generated manually by means of handles (not shown) attached to cover 610, or electrically by means of a plurality of solenoids 670 and/or by means of a spring assembly 660 deployed around the periphery of cover 610, as well known to those skilled in the art to achieve balanced displacement of the cover. Solenoids 670 are mounted such that one side of a solenoid is mechanically connected to displaceable cover 610 and the other side thereof is connected to a chamber wall 620. When electrical actuation of cover 610 is employed, command 608 generated by skin contact sensor 460 (Fig. 25) is transmitted to spring assembly 660 or solenoids 670 after a predetermined time delay following contact between cover 610 and skin surface 630, causing cover 610 to be proximally displaced upward with a proximally directed lifting force 652 comparable to that of a piston. By properly controlling solenoids 670, height H of the drawn skin target 650 relative to the adjoining skin surface 630 can be adjusted. Height H of the drawn skin is generally increased as the treatment spot is increased. For example, height H may be 2 mm for a treatment spot of 40 mm, while height H may be 0.5 mm for a treatment spot of 3 mm. Alternatively, height H may be adjusted to ensure that skin target 650 contacts clear transmitting element 615 for pain alleviation.

[0161] At times, a sufficiently high vacuum level for effecting a light-based treatment may not be produced within vacuum chamber 640, due to a malfunction. If a health professional notices that the distance between skin target 650 and clear transmitting element 615 is greater than a predetermined distance for effective treatment with an IPL or laser, the automatic control of cover 610 may be overridden. By reversing the direction of current within solenoids 670, one-time distally directed force 678 may be generated which urges cover 610 towards skin surface 630.

[0162] When the distal end of the treatment light source is positioned on chamber walls 620, cover 610 has a relatively low weight of approximately 50 gm. However, if the treatment handpiece is positioned on cover 610 such that the combined weight of the cover and handpiece is approximately 1 kg, the capacity of solenoids 670 needs to be increased, in order to raise both the cover and handpiece and to produce a vacuum within chamber 640.

[0163] Apparatus 600 advantageously provides low power consumption and increased compactness. When the handpiece is positioned on chamber walls 620, solenoids 670 are energized by a battery without need of draining wall current and only when cover 610 is needed to be vertically displaced. The energy requirement for raising cover 610 to a height of 2 mm is approximately 0.5 J for a typical 500-pulse large area treatment on the back or legs. Therefore an inexpensive 1.5 V battery is suitable for more than 1000 treatments.

[0164] Apparatus 600 also advantageously prevents accumulation of gel. When skin target 650 is drawn during a vacuum applying mode as shown in Fig. 27B, gel 635 is displaced to a peripheral skin area within vacuum chamber 640. However, when cover 610 returns to its original lowermost position as shown in Fig. 27C, skin target 650 is retracted. Gel 635 is then substantially uniformly spread underneath cover 610, due to the pressure applied by cover 610. Similarly when apparatus 600 is repositioned to another skin target, gel 635 does not accumulate.

[0165] The proximally directed force may be supplemented by means of a vacuum pump, which may be needed if an excessive amount of gel is applied to skin surface 630 or if it desired to indicate that skin target 650 has undergone a light-based treatment as described hereinabove.

[0166] Fig. 28 illustrates another embodiment of the invention which is suitable for pain alleviation. Apparatus 700 comprises vacuum chamber 705 and IPL treatment light source 710, e.g. one produced by Syneron USA, which is provided with an RF source at the distal end thereof in the form of two electrodes 720. When clear transmitting element

725 of vacuum chamber 705 is made of sapphire, which has electrical insulating properties, the RF waves are prevented from propagating to skin target 735. To allow sapphire to be a suitable transmitting element for apparatus 700, two metallic conducting electrodes 730 are welded in two slits, respectively, formed in the sapphire transmitting element 725. Electrodes 730 are positioned to be within the propagation path of electrodes 720 integrally formed in light source 710. Suitable means, such as a magnetic rod (not shown), may be used to ensure the quick centering of light source 710 with respect to electrodes 730 of sapphire transmitting element 725. During application of the vacuum, skin target 740 contacts the sapphire transmitting element 725 and electrodes 730 transmit RF waves to skin target 740.

[0167] Fig. 19 illustrates an exemplary skin cooling device which is suitable for the pain alleviating apparatus of the present invention. Since the vacuum chamber is configured so as to ensure that a skin target contacts the clear transmitting element when a vacuum is applied, as described hereinabove, skin cooling is optimized when clear transmitting element 1906 is directly cooled. Accordingly, thermally conducting plate 1975, which is cooled by thermoelectric chiller 1979, contacts clear transmitting element 1906, in order to conduct the heat generated by the treated skin target 1960 from the clear transmitting element. The treatment handpiece is provided with chiller 1979 so as to prevent an increase in temperature of the epidermis, which may be damaged if the skin is relatively dark, e.g. Fitzpatrick skin type 4-6. In order to improve the compactness of the skin cooling device, plate 1975 is positioned obliquely with respect to clear transmitting element 1906 without interfering with the propagation of light beam 1908. It will be appreciated that pain alleviation is achieved by application of a vacuum, which brings the skin in contact with the clear transmitting element, and not by means of the chiller. As described in Example 8 hereinbelow, pain relief was noticeable during experimentation performed in conjunction with vacuum-assisted, light-based treatments without employment of a skin chiller.

[0168] The clear transmitting element may be alternatively cooled by applying a low temperature spray, such as produced by Dermachill, USA, to conducting plate 1975 or by means of a chilling liquid flowing over the conducting plate.

[0169] In Fig. 20, apparatus 1990 comprises a thin polycarbonate layer 1994, e.g. having a thickness of 10 microns, attached to the distal face of clear transmitting element 1993 and transparent to the treatment light directed to skin target 1960. Vacuum chamber 1991 is suitably sized and the applied vacuum level is sufficient to draw skin target 1960 to be in pressing contact with polycarbonate layer 1994. Polycarbonate layer 1994 is sufficiently thin to conduct heat from skin target 1960 to clear transmitting element 1993, is sufficiently soft to provide good mechanical matching between skin target 1960 and clear transmitting element 1993, and also provides good optical matching therebetween.

[0170] As described hereinabove, applying a vacuum to the vacuum chamber may either increase or decrease the blood volume fraction within a skin target, depending on a selected configuration of the vacuum chamber. Accordingly, a health professional may employ two differently configured vacuum chambers, each of which is releasably attachable to the same light source handpiece, in order to effect two distinct types of vacuum-assisted light-based treatment, respectively, with a minimum delay to the patient. Thus a single light source and a single vacuum pump may be used for both treatment of vascular lesions by increasing blood concentration within a skin target and for painless hair removal.

[0171] In summation, Table I below tabulates the main differences between prior art vacuum-assisted-light-based treatment methods, by which ablated skin and vaporous debris are evacuated from a skin target, and that of the present invention:

Table I

	Present Invention	Prior Art Smoke Evacuators
Treatment Depth	Subcutaneous	Skin surface
Light source	Non-ablative, 400-1800 nm	Ablative, above 1800 nm
High Vacuum Level (approximately 0 atm)	Yes	No; evacuated air is replaced by fresh air
Automatic Release of Vacuum, to Allow Displacement of Treatment Handpiece	Yes; by means of control unit	Not necessary due to low vacuum level
Contact between Skin and Clear Transmitting Element	Yes; for pain alleviation	No
Suitable for Employment of Gel	Yes	No
Vacuum-Assisted Pain Alleviation	Yes	No
Enhanced Skin Redness	Yes	No

Table continued

	Present Invention	Prior Art Smoke Evacuators
5 10 15 20 25 30 35 40 45	Suitable for Non- Ablative IPL and Nd: YAG, Dye, Alexandrite, Ruby, and Diode Lasers	Yes No; Suitable for Ablative Lasers

[0172] Figs. 26A-B illustrate another embodiment of the invention by which a vacuum chamber need not be repositioned from one skin target to another. Fig. 26A is a schematic plan view of the apparatus and Fig. 26B is a cross sectional view thereof. As shown, array 500 of vacuum chambers is embodied by a single flat sheet 505, e.g. disposable and produced from low cost, transparent or translucent molded silicon, which is placed on skin surface 520 and formed with a plurality of vacuum chambers 510. The interior of each vacuum chamber 510 is defined by a bottom which is coplanar with bottom edge 515 of sheet 505, two side walls 522 extending proximally from bottom edge 515, and top edge 522 separated distally from upper surface 525 of sheet 505. A clear transmitting element 540 corresponding to each vacuum chamber 510 is secured to sheet 505, directly above top edge 522 of the vacuum chamber. Clear transmitting element 540 may be an inexpensive thin polycarbonate plate or a diffuser. The bulk material of sheet 505 is also formed with a plurality of conduits 530, each of which in communication with a corresponding vacuum chamber 510 and through which air is evacuated from the corresponding vacuum chamber. The distance between adjacent vacuum chambers 510 is sufficiently small to allow light which has diffused from the interior of each chamber to treat a skin area located underneath a corresponding conduit 530. Each conduit 530 branches into portions 532 and 534, wherein all conduit portions 532 are in communication with a vacuum pump (not shown) and all conduit portions 534 are in communication with a source of compressed air (not shown).

[0173] Array 500 advantageously allows a large-area skin surface, such as of an arm or leg, to be treated by a light source. The treatment light source is sequentially directed to each vacuum chamber 510. Following propagation of the light through a selected vacuum chamber in order to treat a corresponding skin target, the light source may be quickly moved or glided to another skin target without having to move a vacuum chamber and overcoming the force which urges it to the skin surface. Since a vacuum chamber is not displaced, gel is similarly not moved and does not accumulate. Consequently, there is no need to provide means for preventing obstruction of gel within the vacuum pump.

[0174] Array 500 is also provided with at least one contact detector (not shown), which triggers a signal to activate the vacuum pump. When the contact detector senses the placement of array 500 on a skin surface, the vacuum pump is activated, and the air from all vacuum chambers 510 is evacuated simultaneously. The health professional then sequentially directs the light source to each vacuum chamber 510. Following completion of the treatment for the entire skin surface, the light source is deactivated and then the vacuum pump is deactivated. Alternatively, each vacuum chamber is provided with a contact detector, two control valves to control the passage of fluid through conduits portions 532 and 534, respectively, and light detector (all of which are not shown). When a treatment handpiece is placed on a transmitting element 540, the corresponding contact detector transmits a signal to activate the vacuum pump, open the control valve which regulates the fluid passage through the corresponding conduit portion 532, and then activates the light source. Upon completion of the light treatment, the light source is deactivated after a predetermined period of time or is manually deactivated. The light detector transmits a signal to close the control valve which regulates the fluid passage through the corresponding conduit portion 532 and to open the control valve which regulates the fluid passage through the corresponding conduit portion 534, in order to release the vacuum. This cycle is repeated for all vacuum chambers 510.

Example 1

[0175] An experiment was performed to determine the time response of skin erythema following application of a vacuum onto various skin locations. A pipe of 6 mm diameter was sequentially placed on a hand, eye periphery, arm, and forehead at a subatmospheric pressure of approximately 100 millibar. The skin locations were selected based on the suitability for treatment: the hands and eye periphery for wrinkle removal, arm for hair removal, and forehead for port wine stain treatment. The vacuum was applied for the different periods of time of 1/10, 1/2, 1, 2, 3 seconds and then stopped. The erythema level and erythema delay time were then measured.

[0176] The response time of the hand and eye periphery was 1/2 sec, the response time of the arm was 1 second and the response time of the forehead was 1/2 second. Accordingly, the experimental results indicate that the necessary delay between the application of the vacuum and firing of the laser or intensified pulsed light is preferably less than 1 second, so as not to delay the total treatment time, since the repetition rate of most laser or intensified pulsed light sources is generally less than 1 pulse /sec.

[0177] The erythema delay time was less than 1 second, and therefore the experimental results indicate that patients

will not sense appreciable aesthetic discomfort following treatment in accordance with the present invention.

Example 2

5 [0178] An intense pulsed light system comprising a broad band Xe flashlamp and a cutoff filter for limiting light transmission between 755 nm and 1200 nm is suitable for aesthetic treatments, such that light delivered through a rectangular light guide is emitted at an energy density of 20 J/cm² and a pulse duration of 40 milliseconds, for hair removal with respect to a treated area of 15 X 45 mm.

10 [0179] While efficacy of such a light system for the smoothening of fine wrinkles, i.e. photorejuvenation, is very limited by prior art devices, due to the poor absorption of light by blood vessels at those wavelengths, enhanced light absorption in targeted skin structures in accordance with the present invention would increase the efficacy.

[0180] A transparent vacuum chamber of 1 mm height is preferably integrally formed with a handpiece through which intense pulsed light is directed. A diaphragm miniature pump, such as one produced by Richly Tomas which applies a vacuum level of 100 millibar, is in communication with the chamber and a control valve is electronically opened or closed. 15 When the control valve is opened, the pressure in the vacuum chamber is reduced to 100 millibar within less than 10 milliseconds. As a result of the application of vacuum, the skin slightly protrudes into the vacuum chamber at an angle as small as 1/15- 1/45 radian (height divided by size of skin target) and a height of 1 mm. Blood is drawn into the drawn skin target, which achieves a much pinker hue and therefore has a higher light absorbence. The increased redness of the skin increases the light absorption by a factor of 3. As a result, the efficacy of the aforementioned light system is similar to that of a prior art system operating at 60 Joules/cm², which is known to provide adequate results in wrinkle removal procedures. At energy density levels as high as 20 J/cm², it is preferable to chill the epidermis in order to avoid a risk of a burn. Epidermis chilling is accomplished by means of an aluminum plate, which is chilled by a thermoelectric chiller. The plate is in contact with the skin and chills the skin just before the handpiece is moved to the chilled skin target, prior to treatment.

25 [0181] The invention has thereby converted an intense pulsed light device for hair removal into an efficient photorejuvenation device as well.

Example 3

30 [0182] An Nd:YAG laser operating at 1064 nm, 40 milliseconds pulse duration, and energy density of 70 J/cm² is suitable for prior art hair removal having a spot size of 7 mm. By prior art hair removal, absorption of light in the hair shaft melanin is limited, with a contributory factor in hair removal being attributed to the absorption of light by blood in the hair follicle bulb zone. Since the energy density level of 70 J/cm² is risky to the epidermis of dark skin, it would be preferable to operate the laser at 40 J/cm².

35 [0183] A vacuum chamber is preferably integrally formed with a handpiece through which intense pulsed light is directed, at a distance of 1 mm from the skin target. A vacuum is applied to the skin target for 2 seconds. The blood concentration near the follicle bulb and in the bulge at a depth of 4 and 2 mm, respectively, is increased by a factor of 2. As a result the laser is operated with the same efficacy at energy levels closer to 40 J/cm² and is much safer.

Example 4

40 [0184] A Dye laser emitting light at a wavelength of 585 nm, with a spot size of 5 mm and pulse duration of 1 microsecond, is used by prior art methods for treatment of vascular lesions, such as telangectasia, and port wine stains, at an energy density level ranging from 10-15 J/cm² and for the smoothening of wrinkles at an energy density level of 3 -4 J/cm². Some disadvantages of the prior art method are the purpura that is often produced on the skin during vascular treatments and the very large number of treatments (more than 10) which are necessary for the smoothening of wrinkles.

45 [0185] By applying a controlled vacuum to a vacuum chamber in contact with a skin target, having either a moderate vacuum level of approximately 600 millibar or a vacuum which is modulated at a frequency of 10 Hz for 1 seconds prior to the firing of the laser, the efficacy of the laser is enhanced. Consequently it is possible to treat vascular lesions at 7 J/cm² without creating a purpura and to remove wrinkles with a much smaller number of treatments (5).

Example 5

55 [0186] A prior art diode laser operated at 810 nm or a Dye laser is suitable for treating vascular rich psoriatic skin, wherein the treated area per pulse is approximately 1 cm². By employing a vacuum chamber attached to the distal end of the handpiece of either of these lasers, blood is drawn to the lesion and treatment efficacy is improved. The vacuum may be applied for 2 seconds prior to firing the laser beam.

Example 6

[0187] A deep penetrating laser, such as a pulsed diode laser at 940 nm, an Nd:YAG laser, or an intense pulsed light source operating at an energy density of 30 J/cm², is suitable for thermally damaging a gland, when a vacuum chamber is attached to the distal end of the handpiece thereof. When vacuum is applied for a few seconds, e.g. 1-10 seconds, above a gland such as a sweat gland, excessive blood is drawn into the gland. After the pulsed laser beam is directed to the skin, the absorption of the laser beam by the drawn blood generates heat in the gland, which is thereby damaged. It is therefore possible to more efficiently thermally damage glands with a laser or intense pulsed light source when vacuum is applied to the skin.

Example 7

[0188] By placing a vacuum chamber on a skin target in accordance with the present invention prior to the firing of an intense pulsed light source, the treatment energy density level for various types of treatment is significantly reduced with respect to that associated with prior art devices. The treatment energy density level is defined herein as the minimum energy density level which creates a desired change in the skin structure, such as coagulation of a blood vessel, denaturation of a collagen bundle, destruction of cells in a gland, destruction of cells in a hair follicle, or any other desired effects.

[0189] The following is the treatment energy density level for various types of treatment performed with use of the present invention and with use of prior art devices:

- a) treatment of vascular lesions, port wine stains, telangiectasia, rosacea, and spider veins with light emitted from a dye laser unit and having a wavelength of 585 nm: 5-12 J/cm² (present invention), 10-15 J/cm² (prior art);
- b) treatment of vascular lesions, port wine stains, telangiectasia, rosacea, and spider veins with light emitted from a diode laser unit and having a wavelength of 940 nm: 10-30 J/cm² (present invention), 30-40 J/cm² (prior art);
- c) treatment of vascular lesions with light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570-900 nm: 5-20 J/cm² (present invention), 12-30 J/cm² (prior art);
- d) treatment of vascular lesions with light emitted from a KPP laser unit manufactured by Laserscope, USA, and having a wavelength of 532 nm: 4-8 J/cm² (present invention), 8-16 J/cm² (prior art);
- e) photorejuvenation with light emitted from a dye laser unit and having a wavelength of 585 nm: 2-4 J/cm² and requiring 6 treatments (present invention), 2-4 J/cm² and requiring 12 treatments (prior art);
- f) photorejuvenation with light emitted from an intense pulsed non-coherent light unit and having a wavelength ranging from 570-900 nm: 5-20 J/cm² (present invention), approximately 30 J/cm² (prior art);
- g) photorejuvenation with a combined effect of light emitted from an intense pulsed non-coherent light unit and having a wavelength ranging from 570-900 nm and of a RF source: 10 J/cm² for both the intense pulsed non-coherent light unit and RF source (present invention), 20 J/cm² for both the intense pulsed non-coherent light unit and RF source (prior art);
- h) hair removal with light emitted from a Nd:YAG laser unit and having a wavelength of 1604 nm: 25-35 J/cm² (present invention), 50-70 J/cm² (prior art);
- i) porphyrin-based photodynamic therapy with light emitting diodes delivering blue light (420 nm), orange light (585 nm), or red light (630 nm) for a treatment duration ranging from 10 msec to 10 min: 5-20 J/cm² (present invention), 20-30 J/cm² (prior art).

Example 8

[0190] A vacuum chamber made of polycarbonate having a length of 50 mm, a width of 25 mm, a height of 3 mm, and a clear transmitting element made of sapphire was used during the treatment of unwanted hairs of 5 patients with an intense pulsed light system which emitted energy in the spectral band of 670-900 nm. A thin layer of gel at room temperature having a thickness of 0.5 mm was applied to a skin target. The suction openings had a diameter of 1 mm and were formed in the vacuum chamber walls at a height of 0.5 mm below the clear transmitting element, in order to prevent the obstruction of the openings by gel or by the drawn skin. A small canister serving as a gel trap was provided intermediate to the fluid passage between the vacuum chamber and the vacuum pump, to prevent gel from being drawn to the inlet port of the vacuum pump. A vacuum level of 500 mmHg was generated within the vacuum chamber and caused the skin target to be drawn in contact with the clear transmitting element.

[0191] An intense pulsed light system having a treatment beam length of 40 mm and width of 15 mm was fired with an energy density of 16 - 20 J/cm² and a pulse duration of 30-40 milliseconds. One patient underwent a back hair removal treatment, wherein areas of the back were treated as a control without application of a vacuum onto the skin surface and other areas were treated while a vacuum was applied to the skin surface. The other patients underwent a hair

removal treatment on their legs, chest and abdomen such that a vacuum was applied to some areas, while the treatment of an adjacent area was not vacuum assisted, as a control. For all five patients, a skin chiller was not employed.

[0192] Fig. 21 is a photograph which illustrates two back areas 1985 and 1986, respectively, of one of the patients two months after being treated for hair removal. A vacuum was not applied to the skin surface of back area 1985, while a vacuum was applied to the skin surface of back area 1986. As shown, both back areas remained hairless two months after treatment.

[0193] The pain sensation of the patients was categorized into five levels: Level 0 indicating that pain was not felt at all, Level 5 indicating that pain was intolerable after a few laser shots whereby a patient grimaced and uncontrollably reacted after each shot, Level 1 indicating that the treatment was sensed but without pain, and Levels 2, 3, and 4 indicating an increasing level of pain. All of the patients consistently suffered Pain Level 3-5 when a vacuum was not applied, and the pain was alleviated (Level 2) or was completely prevented (Level 1 or 0) when a vacuum was applied. Pain alleviation was found to be dependent on the time delay between the application of the vacuum and the firing of the intense pulsed light. Pain alleviation was sensed when the intense pulsed light was fired at least 1.5 seconds after application of the vacuum onto the skin surface.

Example 9

[0194] A patient undergoing a hair removal treatment was tested for pain sensitivity. An intense pulsed Diode laser (Light Sheer, Lumenis) operating at 810 nm was employed. A vacuum chamber made of polycarbonate having a length of 40 mm, a width of 15 mm, a height of 3 mm, and a clear transmitting element made of sapphire was used. A thin layer of gel at room temperature having a thickness of 0.5 mm was applied to a skin target. The suction openings had a diameter of 1 mm and were formed in the vacuum chamber walls at a height of 0.5 mm below the clear transmitting element. A small canister serving as a gel trap was provided intermediate to the fluid passage between the vacuum chamber and the vacuum pump, to prevent gel from being drawn to the inlet port of the vacuum pump.

[0195] When a vacuum was not applied to the skin target and the light source operated at an energy density of 42 J/cm² and a pulse duration of 30 milliseconds, the patient sensed a Pain Level of 5. When a vacuum level of 500 mmHg was generated within the vacuum chamber causing the skin target to be drawn in contact with the clear transmitting element and the light source operated at an energy density of 42 J/cm² and a pulse duration of 30 milliseconds, the patient sensed a considerably reduced Pain Level of 2. This reduced pain level during the vacuum assisted treatment was found to be equivalent to the mild pain sensed when the light source operated at an energy density of only 26 J/cm² and a pulse duration of 30 milliseconds and a vacuum was not applied to the skin target.

[0196] While some embodiments of the invention have been described by way of illustration, it will be apparent that the invention can be carried into practice with many modifications, variations and adaptations, and with the use of numerous equivalents or alternative solutions that are within the scope of persons skilled in the art, without departing from the spirit of the invention or exceeding the scope of the claims.

Claims

1. An apparatus for vacuum-assisted light-based skin treatments, comprising:
 - a) a non-ablative intense pulsed monochromatic or non-coherent light source;
 - b) a vacuum chamber placeable on a skin target which has an opening on the distal end thereof and provided with a clear transmitting element on the proximate end thereof, said transmitting element being transparent or translucent to light generated by said source and directed to said skin target;
 - c) means for applying a vacuum to said vacuum chamber, the level of the applied vacuum suitable for drawing said skin target to said vacuum chamber via said opening; and
 - d) means for preventing influx of air into vacuum chamber during a vacuum applying mode.
2. The apparatus according to claim 1, wherein the vacuum applying means comprises a vacuum pump.
3. The apparatus according to claim 2, wherein the vacuum applying means further comprises at least one control valve and control means for controlling operation of the vacuum pump, the at least one control valve, and the light source, said control means being suitable for firing the light source after a first predetermined delay ranging from approximately 0.5 sec to approximately 4 seconds following operation of the vacuum pump, for increasing the pressure in the vacuum chamber to atmospheric pressure following deactivation of the light source to allow for effortless repositioning of the vacuum chamber to a second skin target, for verifying that a desired energy density level of the light is being directed to the skin target, and for deactivating the light source if the energy density level

is significantly larger than said desired level, said control means being selected from the group of electronic means, pneumatic means, electrical means, and optical means and being actuated by means of a finger depressable button positioned on a light treatment handpiece.

- 5 4. The apparatus according to claim 1, wherein influx of air into the vacuum chamber during a vacuum applying mode is prevented by means of a control valve and control circuitry.
- 10 5. The apparatus according to claim 1, wherein the wavelength of the light ranges from 400 to 1800 nm, the pulse duration of the light ranges from 10 nanoseconds to 900 msec, the energy density of the light ranges from approximately 2 to approximately 150 J/ cm², and the level of applied vacuum within the vacuum chamber ranges from approximately 0 to approximately 1 atmosphere.
- 15 6. The apparatus according to claim 1, wherein the vacuum chamber is connected to, or integrally formed with, a proximately disposed handpiece through which light propagates towards the skin target, and the vacuum chamber optionally has a proximate cover formed with an aperture which is attachable to a handpiece having an integral clear transmitting element.
- 20 7. The apparatus according to claim 5, wherein the light source is selected from the group of Dye laser, Nd:YAG laser, Diode laser, light emitting diode, Alexandrite laser, Ruby laser, Nd:YAG frequency doubled laser, Nd:Glass laser, a non-coherent intense pulse light source, and and a non-coherent intense pulse light source combined with an RF source, the light is suitable for hair removal, collagen contraction, photorejuvenation, treatment of vascular lesions, treatment of sebaceous or sweat glands, treatment of warts, treatment of pigmented lesions, treatment of damaged collagen, treatment of acne, treatment of warts, treatment of keloids, treatment of sweat glands, and treatment of psoriasis, and the vascular lesions are selected from the group of port wine stains, telangiectasia, rosacea, and spider veins.
- 25 8. The apparatus according to claim 1, wherein the clear transmitting element is separated from the adjoining skin surface by a gap ranging from 0.5 to 50 mm and is suitable for transmitting the light in a direction substantially normal to a skin surface adjoining the skin target.
- 30 9. The apparatus according to claim 1, wherein the vacuum chamber has at least one suction opening and is provided with a rim for sealing the peripheral contact area between the skin surface adjoining the skin target and a vacuum chamber wall, the vacuum being applied to the vacuum chamber via said at least one suction opening.
- 35 10. The apparatus according to claim 1, wherein the vacuum chamber is U-shaped.
- 40 11. The apparatus according to claim 3, wherein the increase in vacuum chamber pressure is triggered by means of a light detector which transmits a signal to the control means upon sensing a significant decrease in optical energy generated by the light source or after a second predetermined delay, following deactivation of the light source.
- 45 12. The apparatus according to claim 1, wherein the width of a treatment spot per pulse of the light is greater than 5 mm or ranges from 15 to 50 mm.
- 50 13. The apparatus according to claim 2, wherein the vacuum pump is a peristaltic pump for drawing air and gel from the interior of the vacuum chamber via a hose connected to a conduit in communication with the interior of the vacuum chamber or is an air pump.
- 55 14. The apparatus according to claim 3, further comprising a skin contact detector for sensing the placement of the vacuum chamber onto the skin target and for generating a first signal to activate the vacuum pump following placement of the vacuum chamber onto the skin target, wherein the control valve is opened following generation of a second signal by means of a light detector which is adapted to sense termination of the light directed to the skin target, atmospheric pressure air thereby being introduced to the interior of the vacuum chamber, said second signal also being suitable for deactivating the vacuum pump.
15. The apparatus according to claim 2, further comprising an array of vacuum chambers placeable on a skin surface, wherein said array is formed from a single sheet made of material which is transparent or translucent to the light, said sheet is formed with a plurality of conduits for air evacuation such that each of said conduits is in communication with a corresponding vacuum chamber, the distance between adjacent vacuum chambers is sufficiently small to

allow light which has diffused from the interior of each chamber to treat a skin area located underneath a corresponding conduit, and each conduit branches into first and second portions which are in communication with the vacuum pump and with a source of compressed air, respectively.

5 16. The apparatus according to claim 15, wherein each vacuum chamber is provided with a contact detector for triggering a signal to activate the vacuum pump, two control valves to control the passage of fluid through the corresponding first and second conduits portions, respectively, and a light detector which generates a signal to introduce compressed air through the corresponding second conduit portion upon sensing the termination of the light directed to the skin target or the first conduit portions are arranged such that the air from all vacuum chambers is evacuated simultaneously upon activation of the vacuum pump.

17. The apparatus according to claim 1, wherein the vacuum applying means comprises:

- a) a vertically displaceable cover to which the clear transmitting element is secured;
- 15 b) chamber walls which surround, and are of a similar shape as, said cover, a vacuum being generated within a vacuum chamber defined by the volume between said cover, said walls, and the skin target upon proximal displacement of said cover relative to said walls; and
- c) an aeration tube for introducing atmospheric air to the vacuum chamber during a vacuum release mode, said aeration tube being in communication with a valve which is actuated upon conclusion of a skin target treatment,

20 wherein the means for preventing influx into the vacuum chamber is a sealing element which is secured to the outer periphery of the cover and resiliently contacts the chamber walls, wherein a proximally directed force or distally directed force is generated by any means selected from the group of a plurality of solenoids, a spring assembly, and a pneumatic device, or a combination thereof, which are deployed around the periphery of the cover and connected to the walls,

25 wherein the proximally directed force is controllable so as to adjust the height of the drawn skin target relative to the adjoining skin surface and is optionally supplemented by means of a vacuum pump.

18. The apparatus according to claim 17, wherein the solenoids are energized by a 1.5 V battery.

19. The apparatus according to any of claims 1 to 14, further comprising means for preventing passage of skin cooling gel to the vacuum applying means which comprises a trap, a first conduit through which gel and air are drawn from the vacuum chamber to said trap, a second conduit through which air is drawn from said trap to the vacuum pump, and optionally a filter at the inlet of said first and second conduits; a detachable vacuum chamber upper portion having an open central area, a clear transmitting element attached to said upper portion, vacuum chamber walls, a vacuum chamber cover perpendicular to said walls and suitably sized so as to support said upper portion, and a plurality of attachment clips pivotally connected to a corresponding vacuum chamber wall for detachably securing said upper portion to said vacuum chamber cover, detachment of said upper portion allowing removal of gel retained within the vacuum chamber interior; a hydrophobic material to which vacuum chamber walls are coated; or a vacuum chamber configured such that at least one suction opening is sufficiently spaced above the distal end of a vacuum chamber wall and from the centerline of the vacuum chamber so as to prevent obstruction of the at least one suction opening by gel and drawn skin upon application of the vacuum.

20. The apparatus according to claim 19, wherein the trap is suitable for the introduction therein of an ion exchange resin with which the gel is boundable.

21. The apparatus according to claim 19, comprising indication means that the skin target has undergone a light-based treatment by means of gel which is discharged from an end of the hose onto a skin surface during a vacuum applying mode or by means of gel which falls to the skin surface during a vacuum release mode in the shape of the distal end of the vacuum chamber walls.

22. The apparatus according to any of claims 1 to 18, further comprising means for skin cooling, said skin cooling means being adapted to reduce the rate of temperature increase of the epidermis at the skin target and the level of the applied vacuum being suitable for evacuating condensed vapors which are produced within the gap between the clear transmitting element and the skin target and condense on the clear transmitting element during the cooling of skin,

55 wherein the skin cooling means is a metallic plate positionable on the skin surface adjoining the skin target and in abutment with the vacuum chamber on the external side thereof or in contact with the clear transmitting element,

said plate being cooled by means of a thermoelectric cooler; a polycarbonate layer transparent to the directed light which is attached to the distal face of the clear transmitting element; or a gel, a low temperature liquid or gas applied onto the skin target.

- 5 **23.** The apparatus according to any of claims 1 to 18, wherein the apparatus is suitable for alleviating or preventing pain caused by a non-ablative light-based treatment of a targeted skin structure, wherein the gap separating the clear transmitting element from the skin surface adjoining the skin target and the magnitude of the proximally directed force resulting from the applied vacuum in combination are suitable for drawing the skin target to the vacuum chamber via the opening on the distal end of the vacuum chamber until the skin target
10 contacts the clear transmitting element for a duration equal to the first predetermined delay, whereby pain signals generated by the nervous system during the treatment of the skin structure are alleviated or prevented, wherein the control means is suitable for firing the light source after the first predetermined delay, following operation of the vacuum applying means, and is suitable for controlling the vacuum level generated by the vacuum applying means,
15 wherein the control means has a plurality of finger depressable buttons, each of which being adapted to set the vacuum applying means and light source at a unique combination of operating conditions so as to generate a predetermined vacuum level within the vacuum chamber and to fire the light source after a predetermined time delay following the operation of the vacuum applying means.
- 20 **24.** The apparatus according to any of claims 1 to 18, further comprising means to stabilize the vacuum chamber on a substantially non-planar skin surface.
- 25 **25.** The apparatus according to any of claims 1 to 22 and 24, wherein the vacuum chamber has at least one support element suitable for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of the skin target and is releasably attachable to a treatment light handpiece.
- 30 **26.** The apparatus according to any of claims 1 to 25, wherein the vacuum chamber is one-hand graspable by means of a handle connected thereto.
- 35 **27.** An apparatus for controlling the depth of light absorption by blood vessels under a skin surface, comprising:
a) a vacuum chamber placed on a skin target which is formed with an aperture on the distal end thereof and provided with a clear transmitting element on the proximate end thereof, said transmitting element being transparent or translucent to intense pulsed monochromatic or non-coherent light directed to said skin target and suitable for transmitting the light in a direction substantially normal to a skin surface adjoining said skin target;
b) means for applying a vacuum to said vacuum chamber, the level of the applied vacuum suitable for drawing said skin target to said vacuum chamber via said aperture; and
c) means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target, optical energy associated with the directed light being absorbed within said predetermined depth and suitable for thermally injuring or treating predetermined skin structures located at said depth.
40
- 45 **28.** The apparatus according to claim 27, wherein the means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target is a means for modulating the applied vacuum.
- 50 **29.** The apparatus according to claim 27, wherein the means for inducing an increase in the concentration of blood and/or blood vessels within a predetermined depth below the skin surface of said skin target is at least one support element positioned at a skin area adjoining the skin target and having a thickness suitable for inducing an increase in the concentration of blood and/or blood vessels within said predetermined depth, and optionally comprising at least one leg having a thickness considerably less than the at least one support element and positioned at the periphery of the vacuum chamber, said at least one leg being separated from an adjacent support element, the at least one support element being adapted to urge blood expelled by said at least one leg towards the skin target.
- 55 **30.** The apparatus according to claim 27, which is suitable for drawing the skin target approximately 1 mm from the adjoining skin surface, wherein the maximum protrusion of the drawn skin from the adjoining skin surface is limited by the clear transmitting element.

31. The apparatus according to claim 28, wherein the frequency of vacuum modulation ranges from 0.2 to 100 Hz.
32. The apparatus according to claim 27, further comprising a control unit for controlling operation of the vacuum applying means and light source, for controlling operation of at least one control valve in communication with the vacuum chamber, for firing the light after a predetermined delay ranging from approximately 10 msec to approximately 1 second following application of the vacuum, and for electronically modulating the vacuum.
33. The apparatus according to claim 27, wherein the duration of vacuum application to the vacuum chamber is less than 2 seconds.
34. The apparatus according to claim 27, wherein the light emitted from the light source has any wavelength band from 400 nm to 1800 nm, wherein the treatment energy density level for treatment of vascular lesions, port wine stains, telangiectasia, rosacea, and spider veins with light emitted from a dye laser unit and having a wavelength of 585 nm ranges from 5 to 12 J/cm², wherein the treatment energy density level for treatment of vascular lesions, port wine stains, telangiectasia, rosacea, and spider veins with light emitted from a diode laser unit and having a wavelength of 940 nm ranges from 10 to 30 J/cm², wherein the treatment energy density level for treatment of vascular lesions with light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570 to 900 nm ranges from 5 to 20 J/cm², wherein the treatment energy density level for photorejuvenation with light emitted from a dye laser unit and having a wavelength of 585 nm ranges from 1 to 4 J/cm², wherein the treatment energy density level for photorejuvenation with light emitted from an intense pulsed non-coherent light unit and having a wavelength of 570 to 900 nm ranges from 5 to 20 J/cm², wherein the treatment energy density level for photorejuvenation with a combined effect of light emitted from an intense pulsed non-coherent light unit and having a wavelength ranging from 570 to 900 nm and of a RF source is approximately 10 J/cm² for both the intense pulsed non-coherent light unit and RF source, wherein the treatment energy density level for hair removal with light emitted from a Nd:YAG laser unit and having a wavelength of 1604 nm ranges from 25 to 35 J/cm², wherein the treatment energy density level for porphyrin-based photodynamic therapy with light emitting diodes delivering light at a wavelength of 420 nm, 585 nm, or 630 nm ranges from 5 to 20 J/cm².
35. The apparatus according to any of claims 27 to 34, further comprising a pulsed radio frequency (RF) source for directing suitable electromagnetic waves at a frequency ranging from 0.2 to 10 MHz to the skin target, wherein the RF source is a bipolar RF generator which generates alternating voltage applied to the skin surface via wires and electrodes or is a monopolar RF generator, wherein the control unit is suitable for transmitting a first command pulse to the at least one control valve and a second command pulse to both the light source and RF source.
36. The apparatus according to claim 32, further comprising an erythema sensor for measuring the degree of skin redness induced by the vacuum applying means, wherein the control unit is suitable for controlling, prior to firing the light source, the energy density of the light emitted from the light source, in response to the output of the erythema sensor.
37. The apparatus according to claim 32, further comprising a skin contact detector for sensing the placement of the vacuum chamber onto the skin target, the control unit being suitable for activating the vacuum applying means in response to a signal transmitted by said skin contact detector.
38. The apparatus according to claim 32, further comprising a light detector for sensing the termination of the light directed to the skin target, the control unit being suitable for regulating a control valve in response to a signal transmitted by said light detector so as to introduce atmospheric pressure air to the interior of the vacuum chamber.
39. The apparatus according to claim 27, further comprising an array of vacuum chambers placeable on a skin surface, wherein the array is formed from a single sheet made of material which is transparent or translucent to the light, said sheet being formed with a plurality of conduits for air evacuation such that each of said conduits is in communication with a corresponding vacuum chamber.
40. The apparatus according to any of claims 27 to 39, further comprising means for skin cooling, said skin cooling means adapted to reduce the rate of temperature increase of the epidermis at the skin target.

41. The apparatus according to any of claims 27 to 39, further comprising means for preventing passage of skin cooling gel to the vacuum applying means.
42. The apparatus according to any of claims 27 to 41, wherein the vacuum chamber is releasably attachable to a treatment light handpiece.
43. The apparatus according to any of claims 27 to 42, wherein the vacuum chamber is one-hand graspable by means of a handle connected thereto.
44. The apparatus according to any of claims 27 to 43, further comprising means to stabilize the vacuum chamber on a substantially non-planar skin surface.

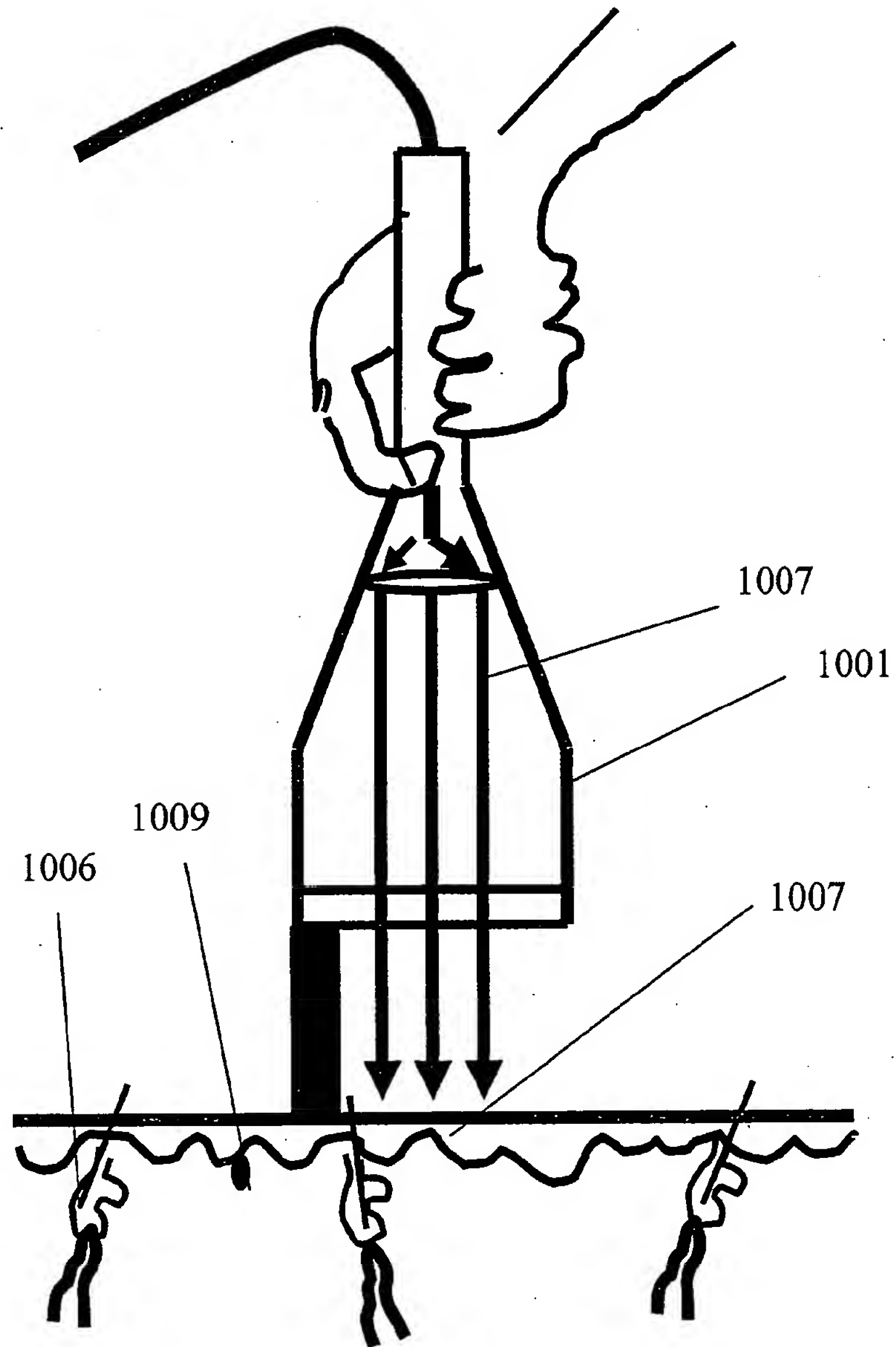


Fig. 1
PRIOR ART

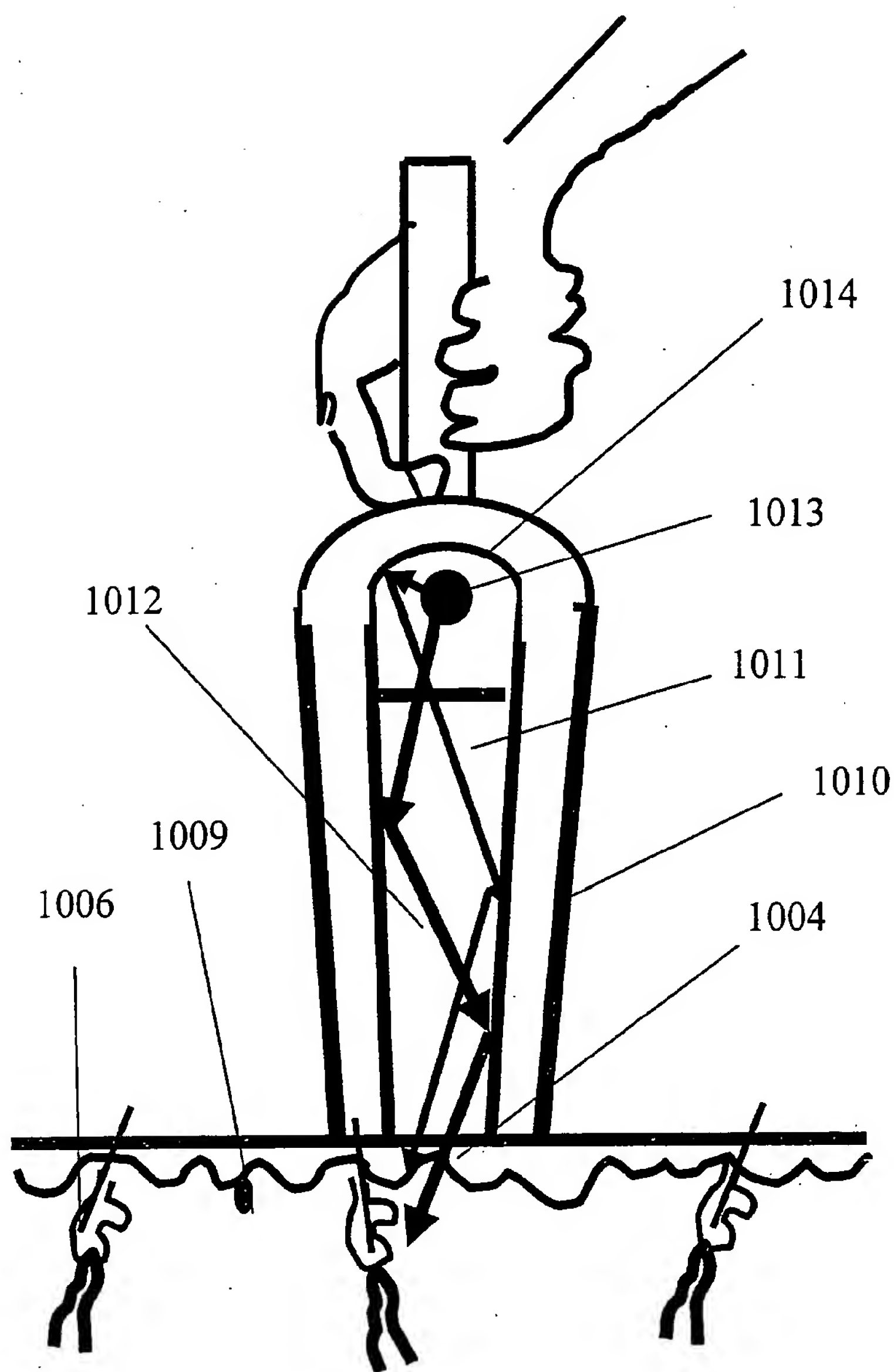


Fig. 2
PRIOR ART

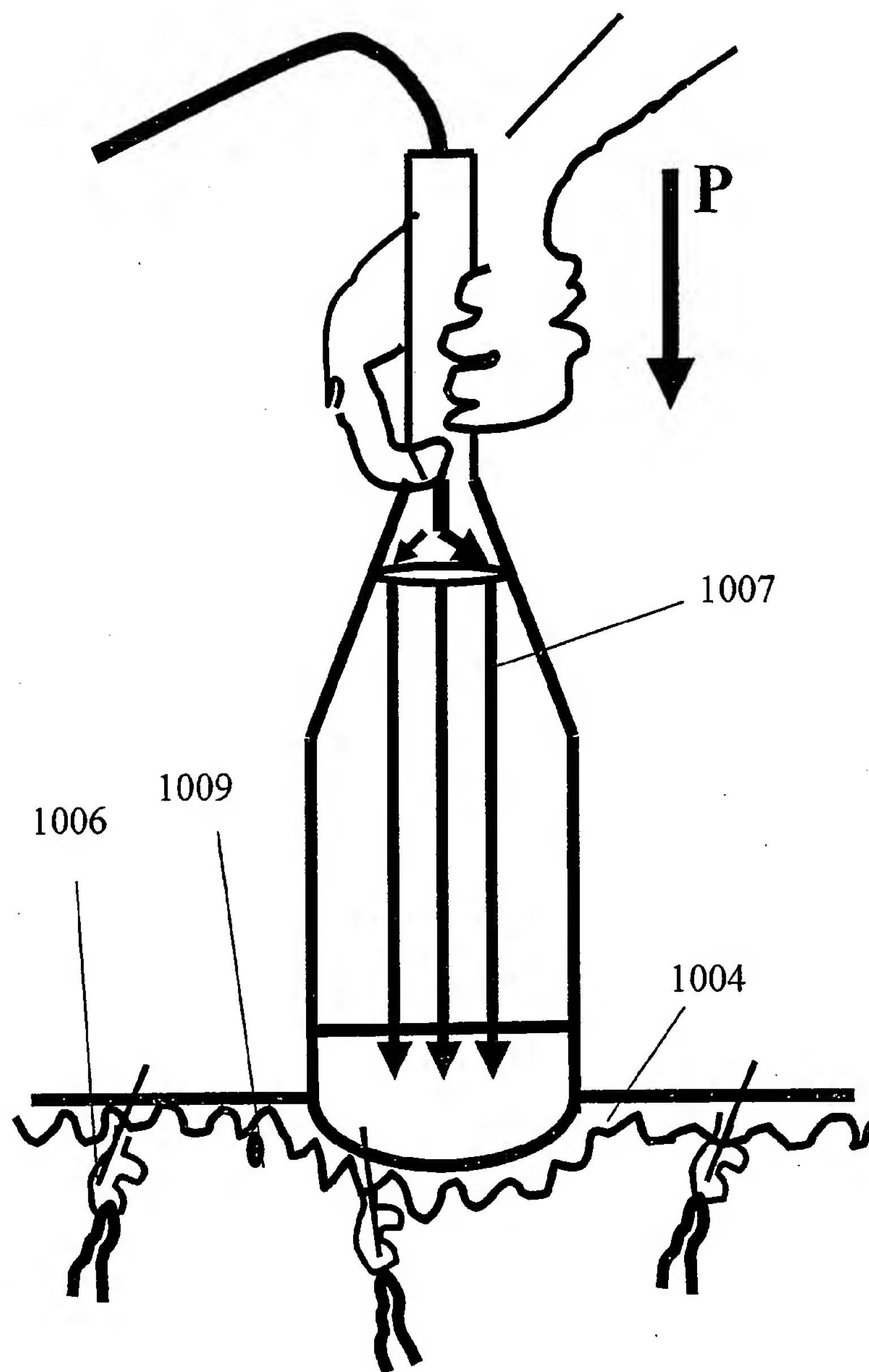


Fig. 3
PRIOR ART

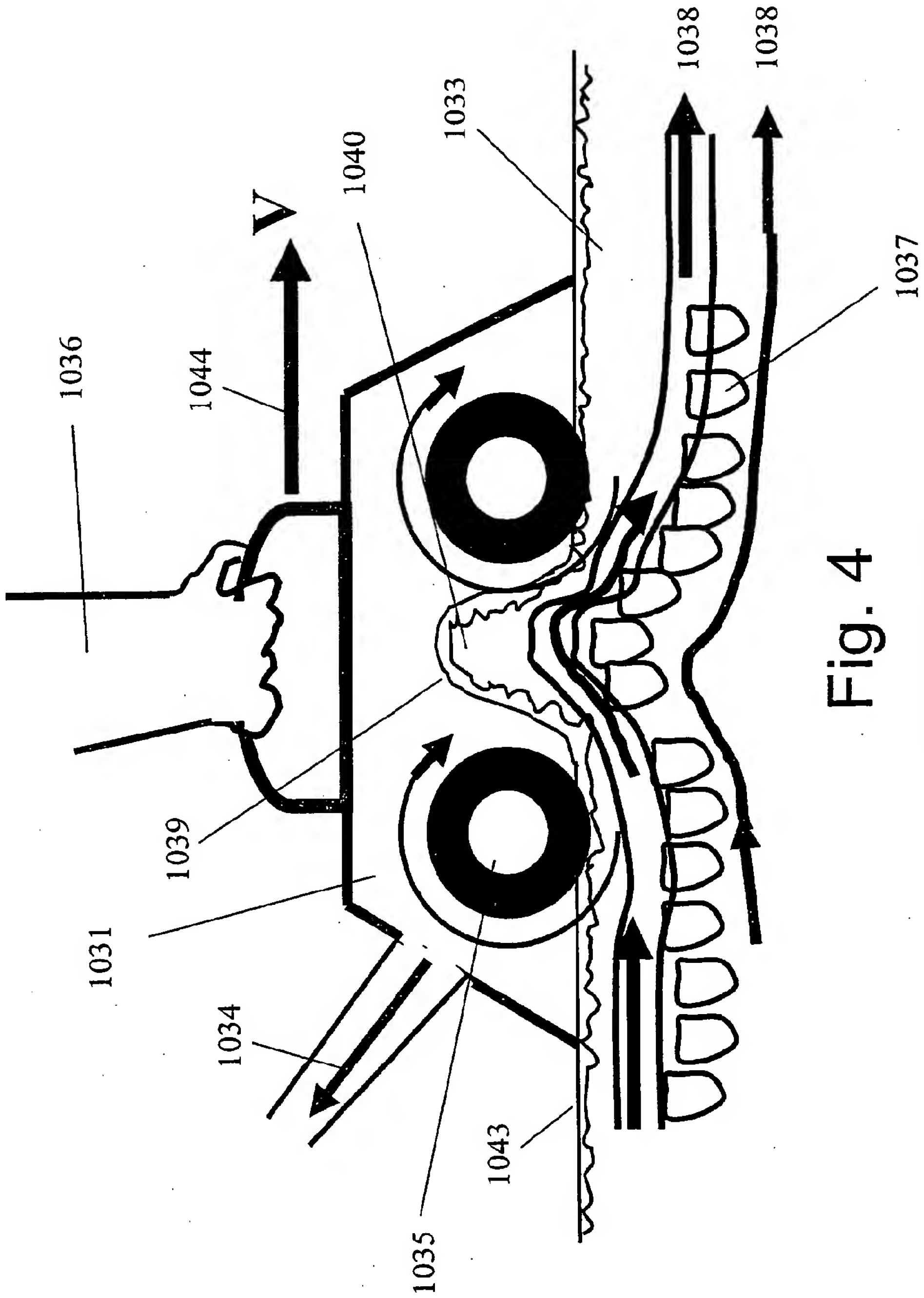


Fig. 4
PRIOR ART

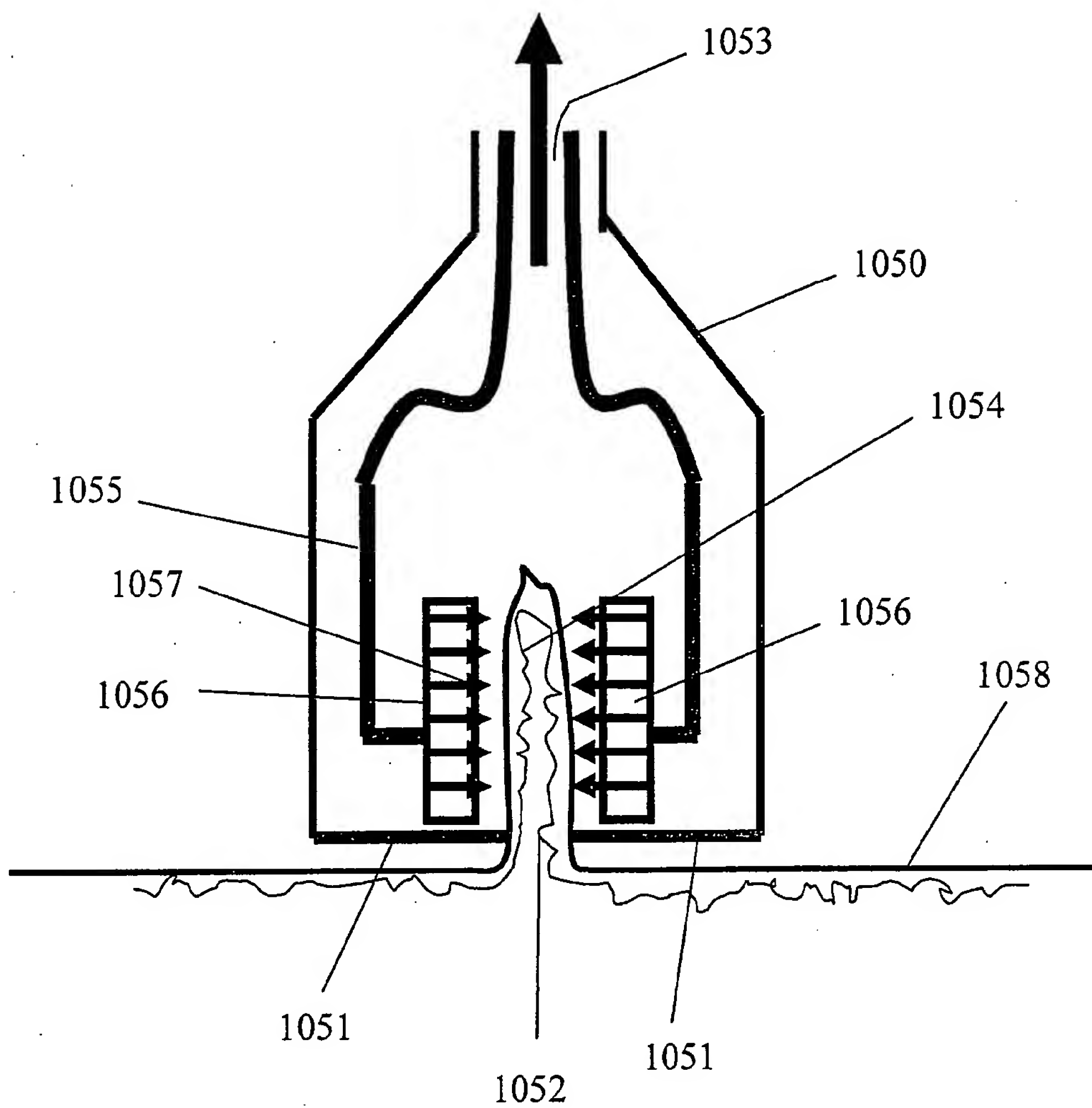


Fig. 5
PRIOR ART

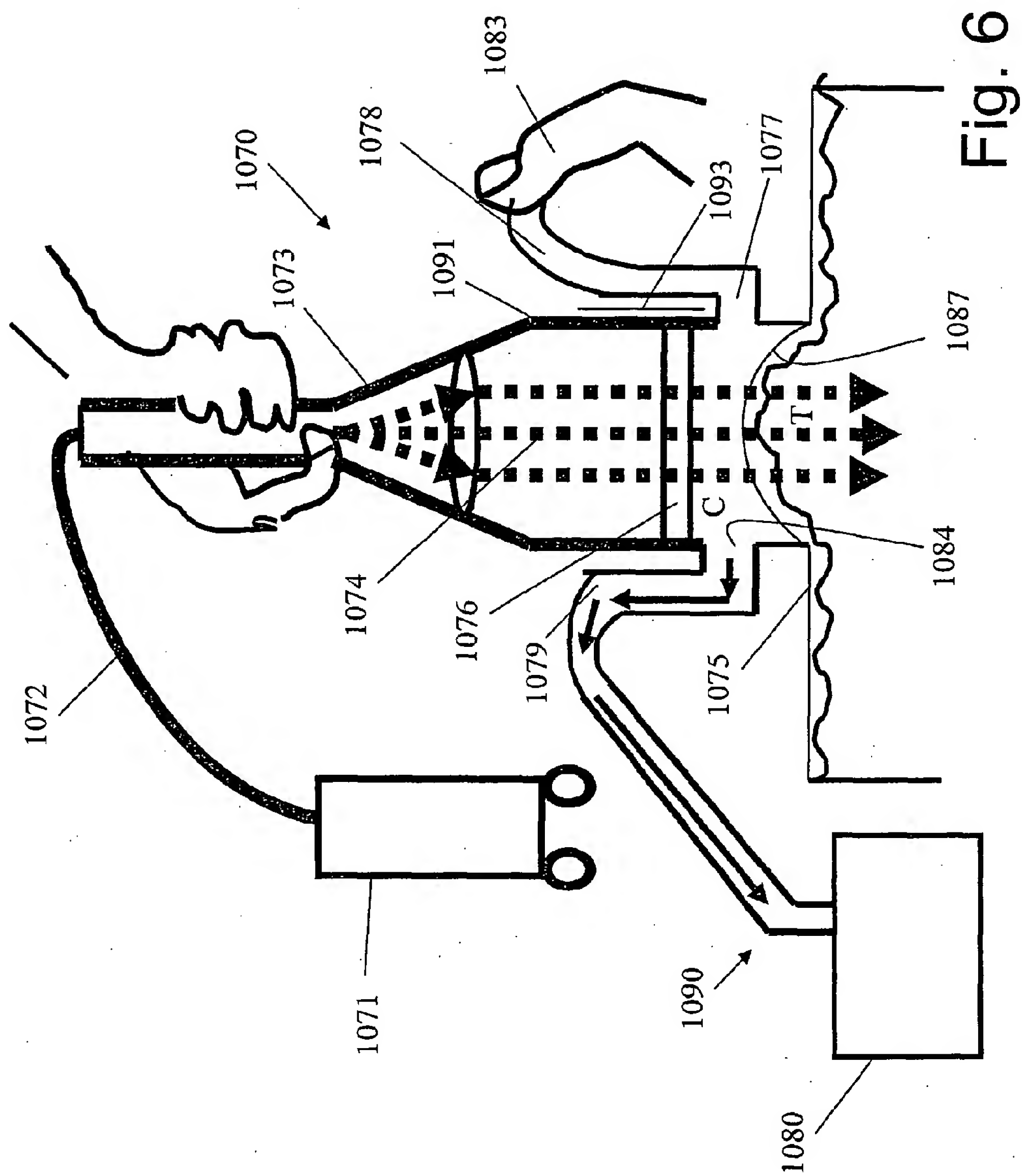
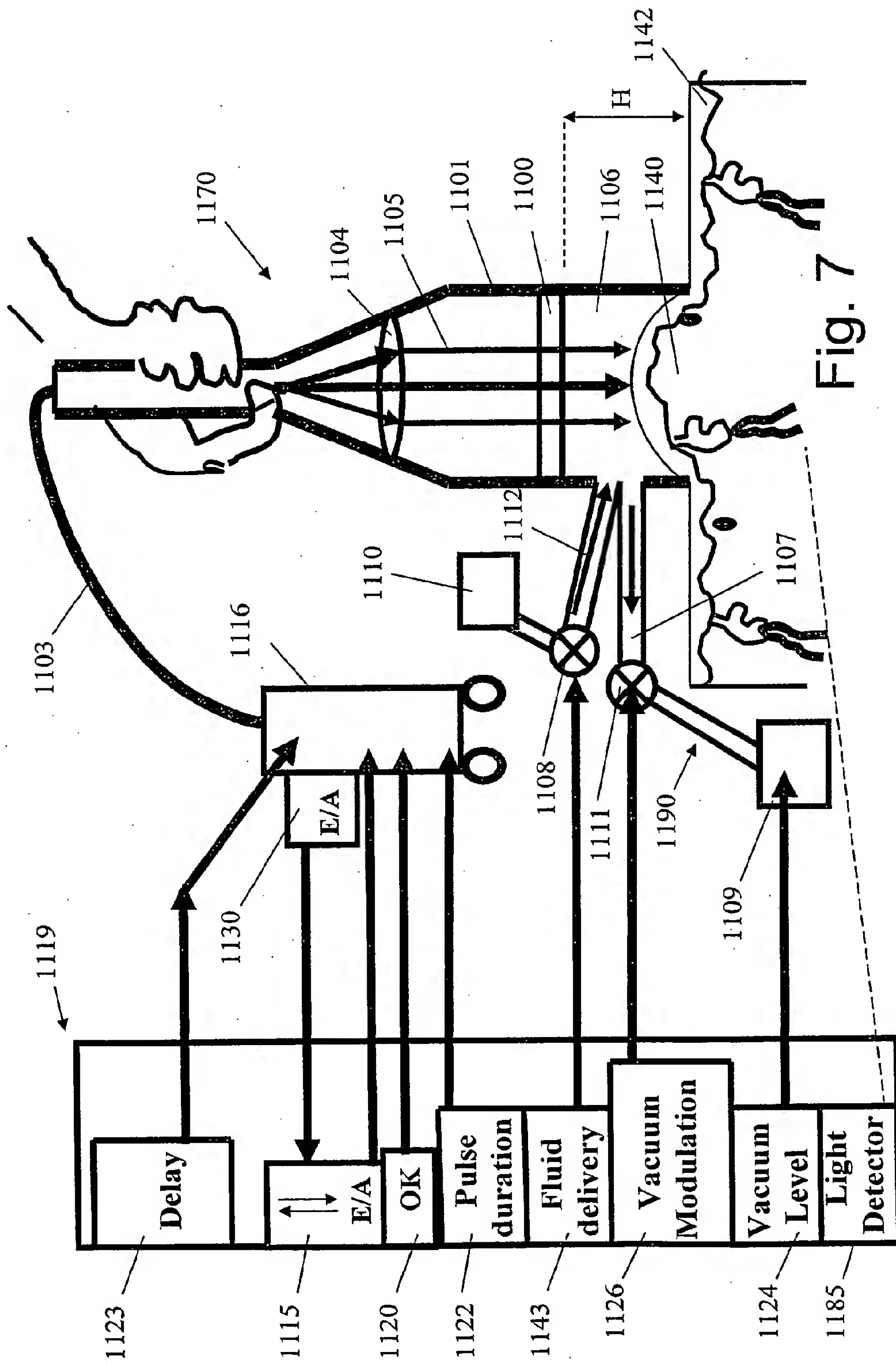


Fig. 6



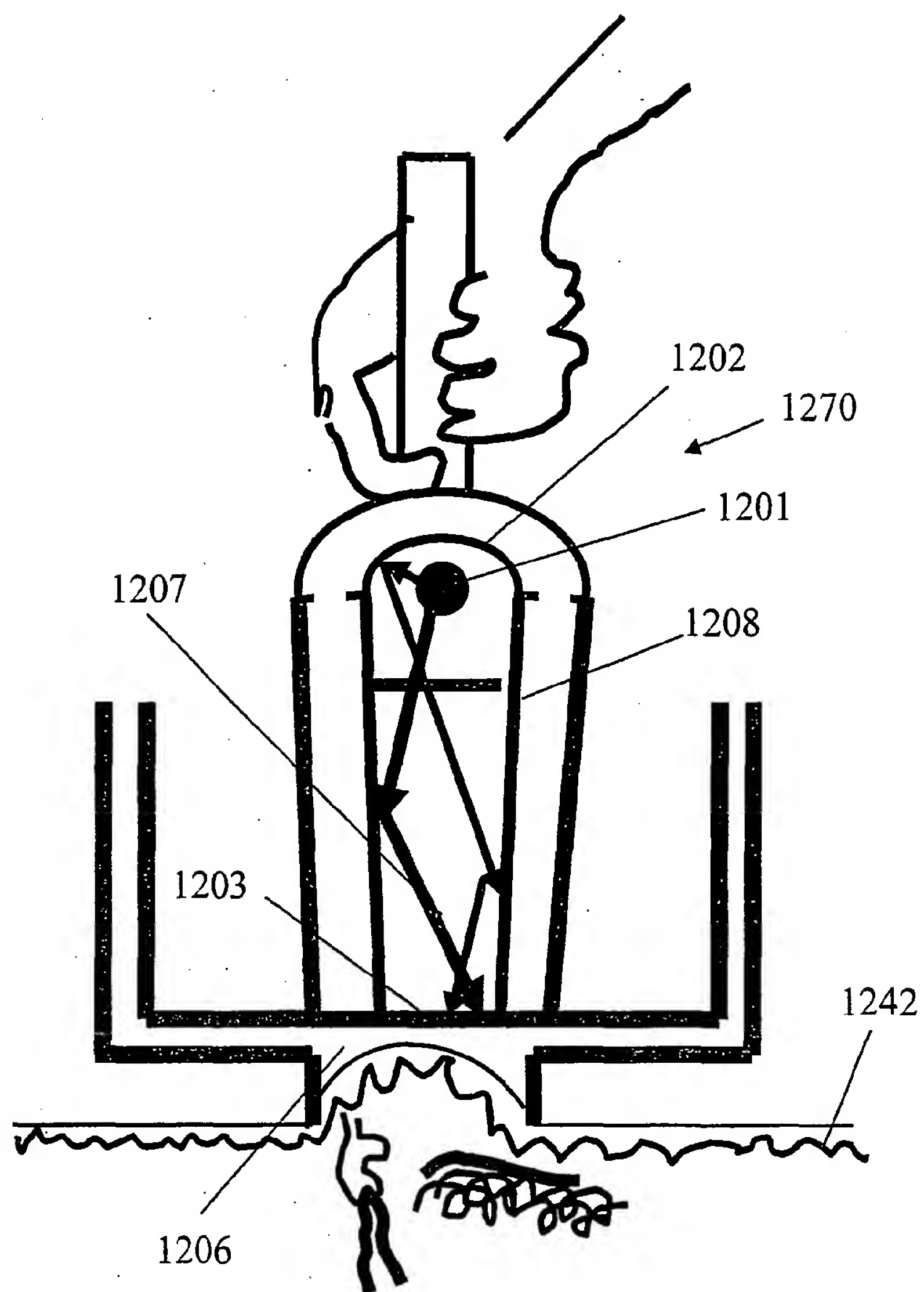
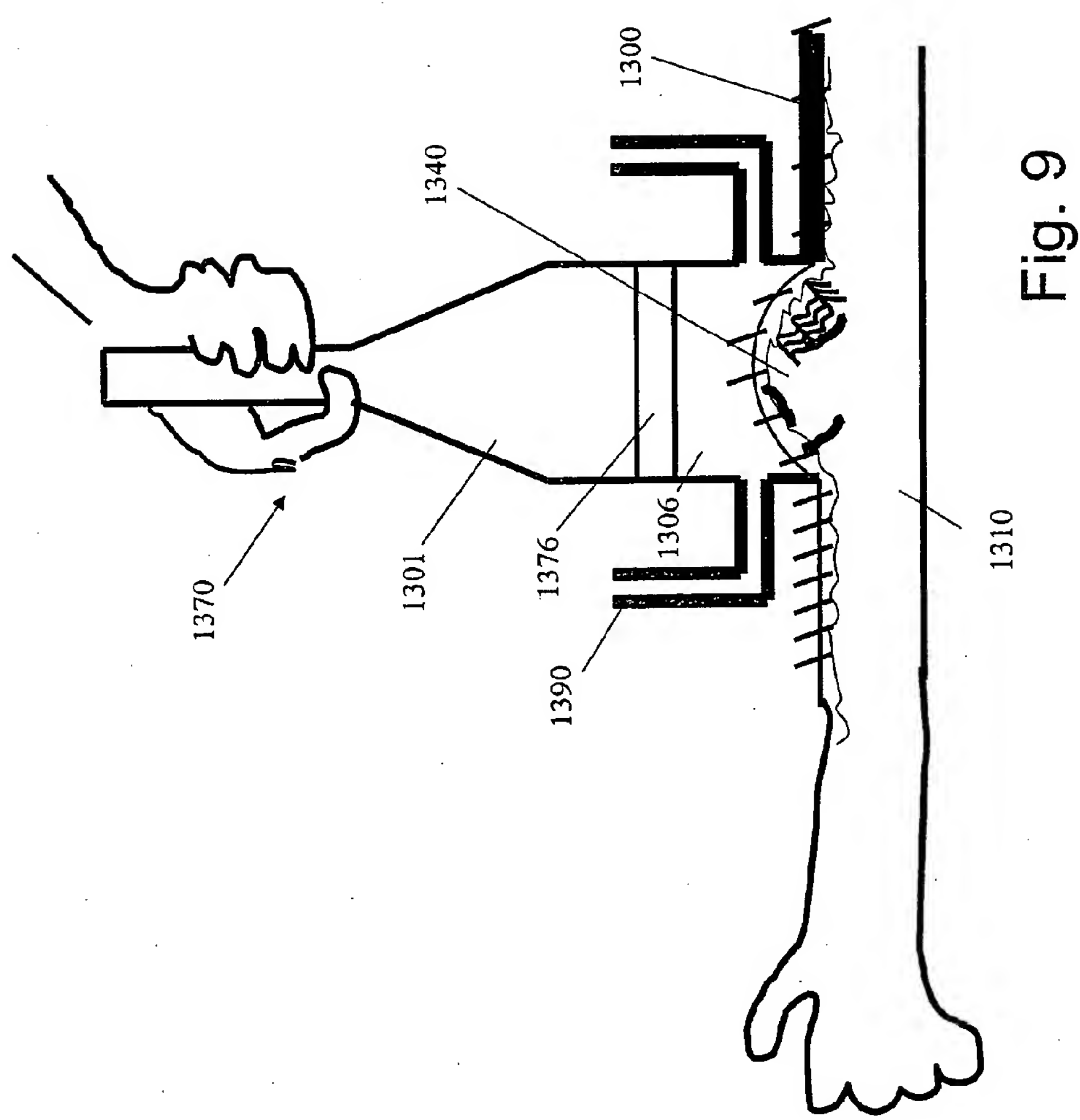


Fig. 8



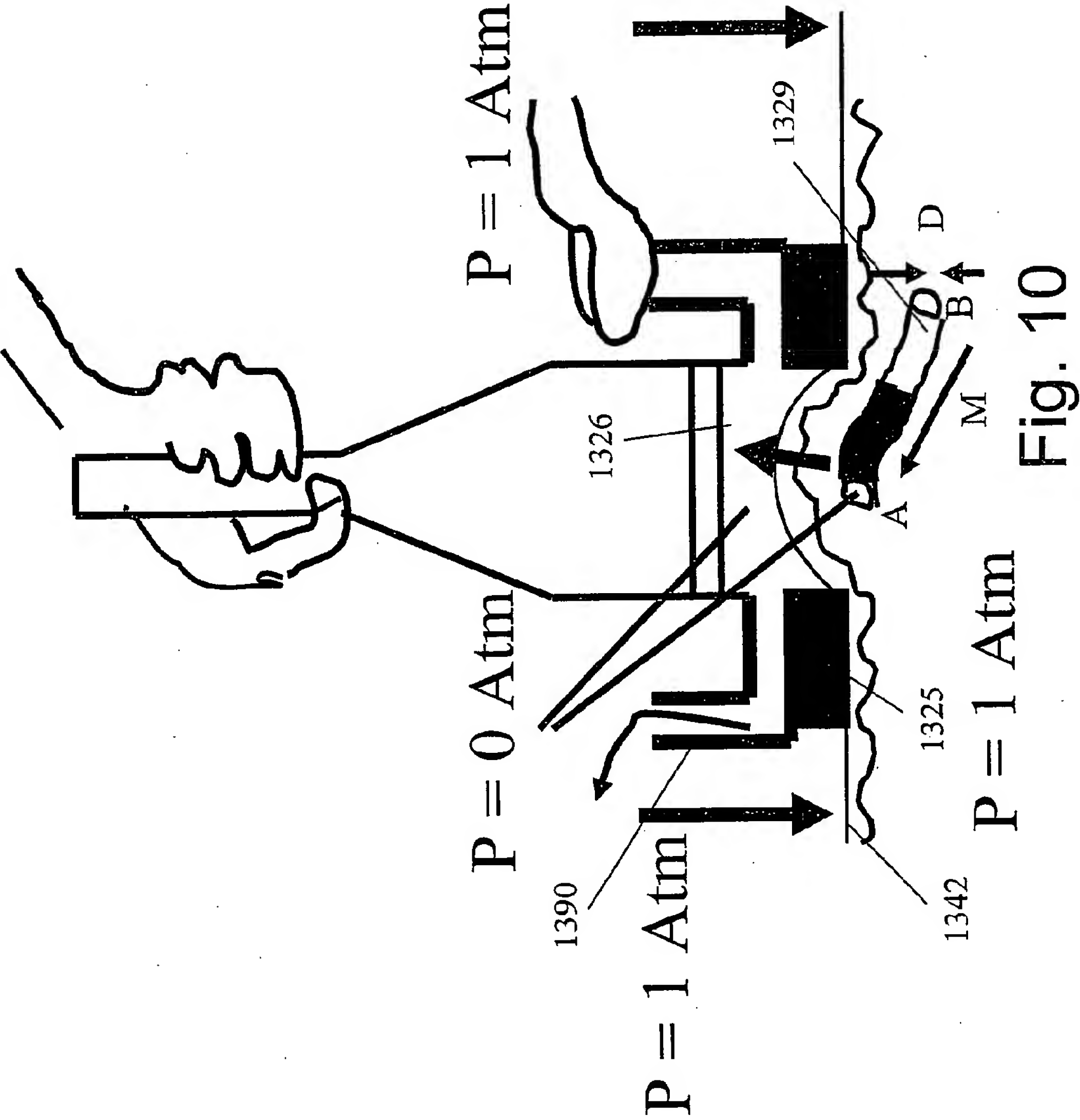


Fig. 10

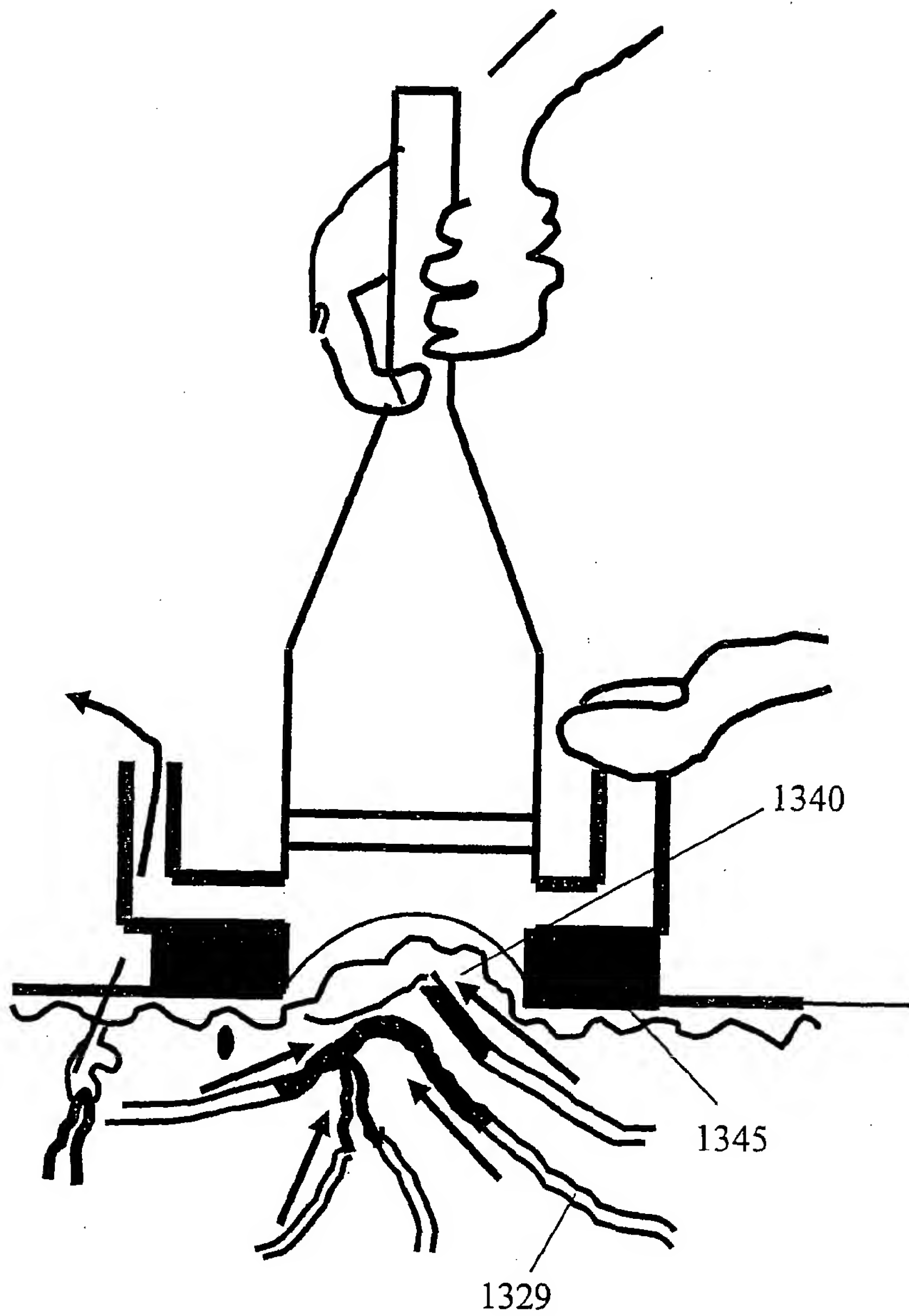


Fig. 11

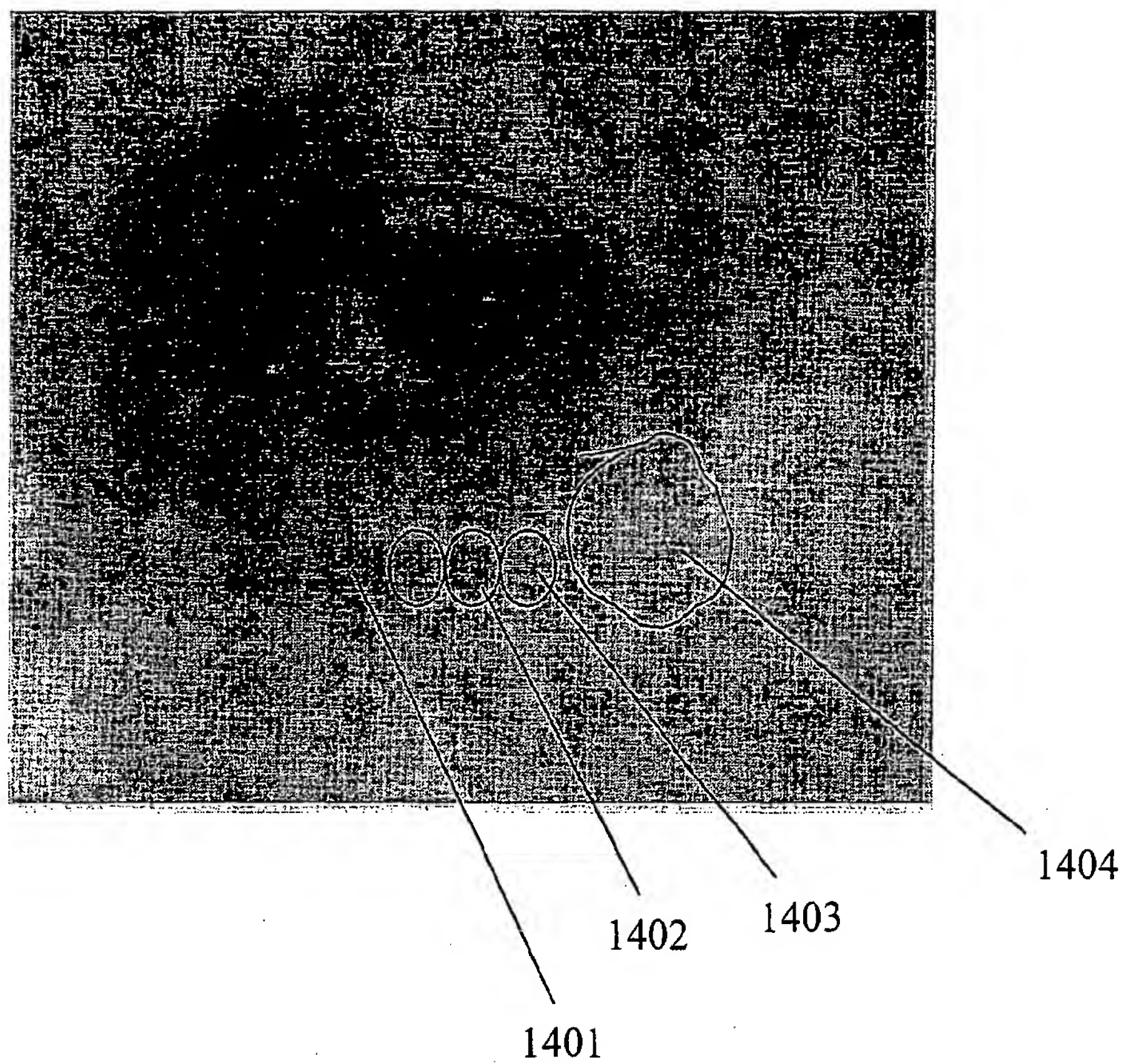
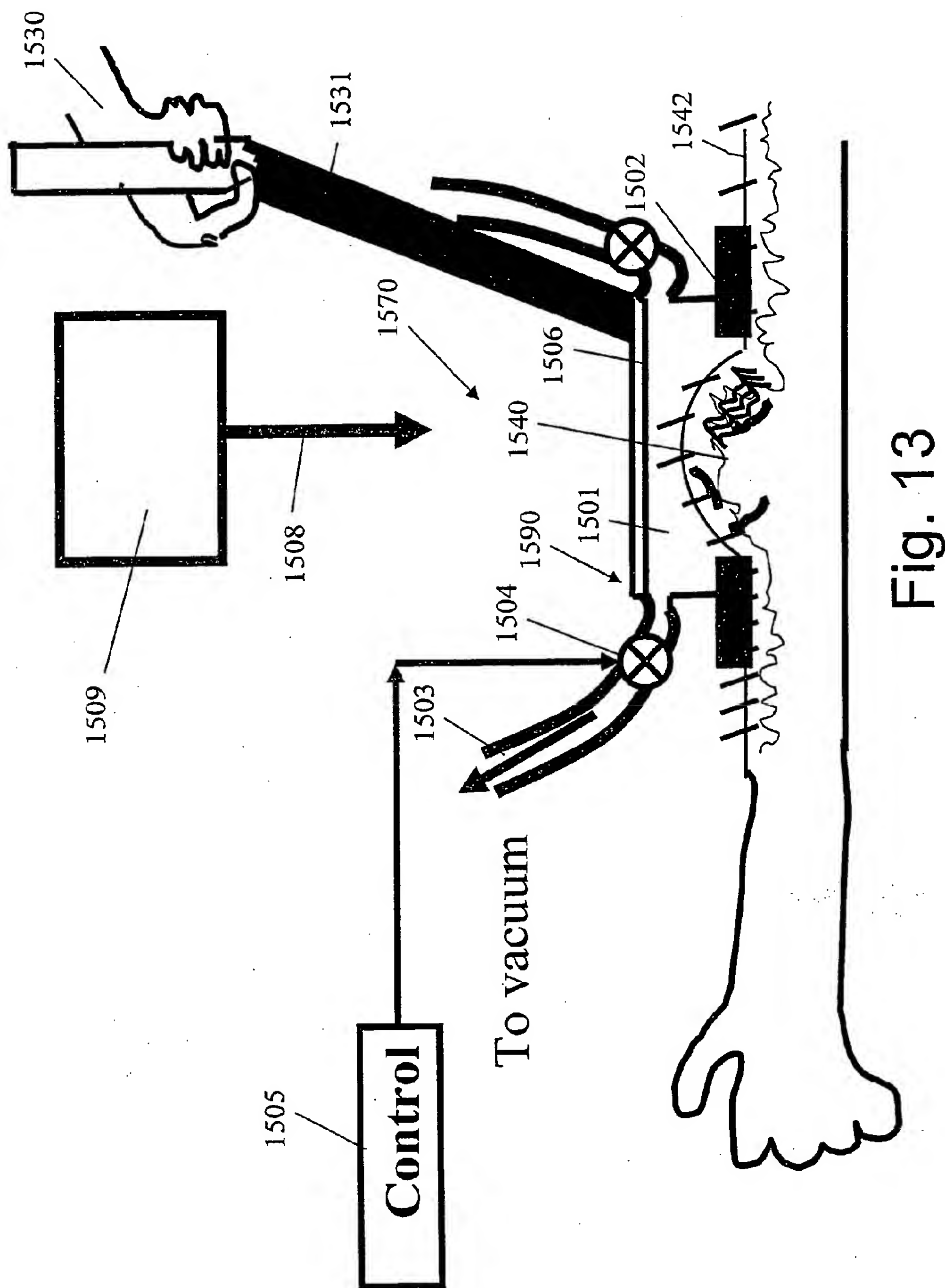
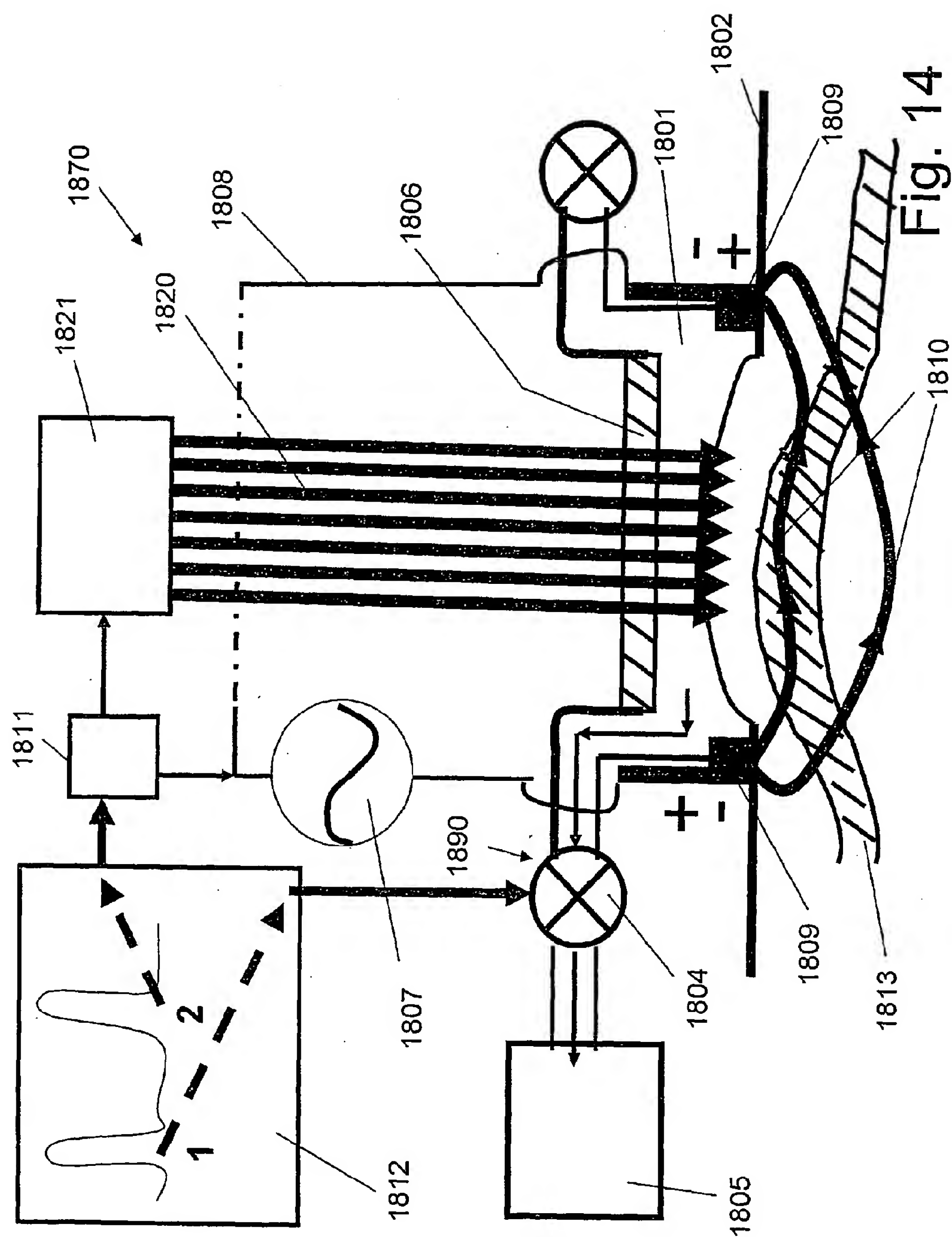
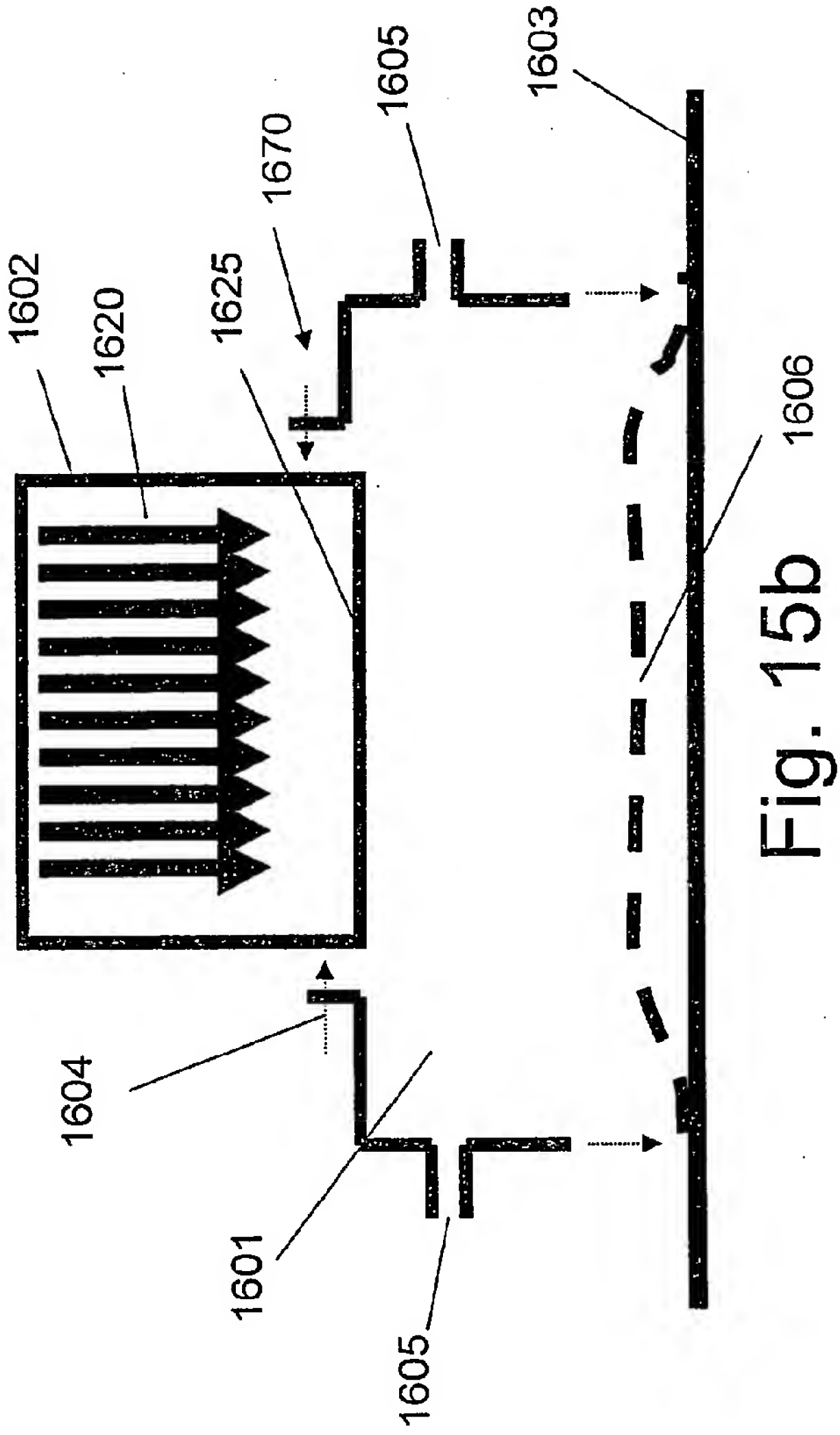
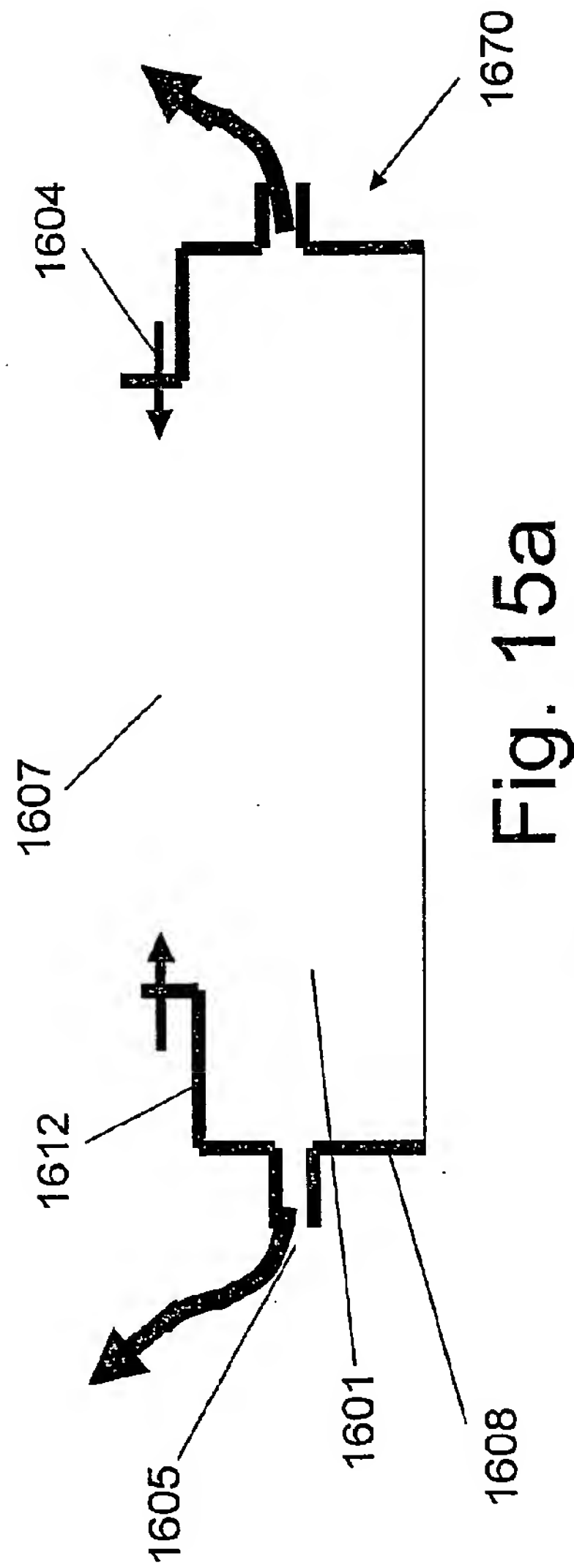


Fig. 12







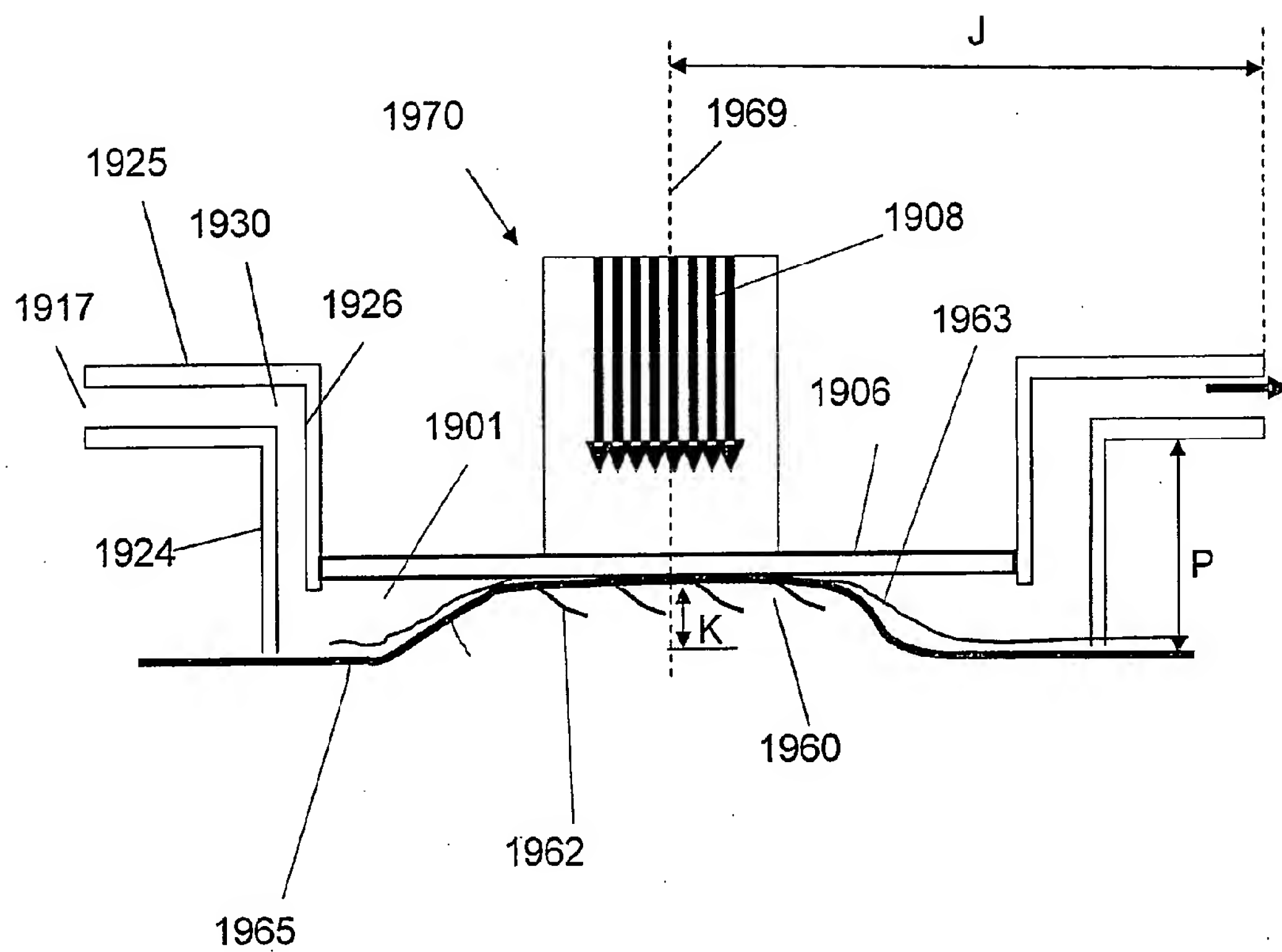


Fig. 16

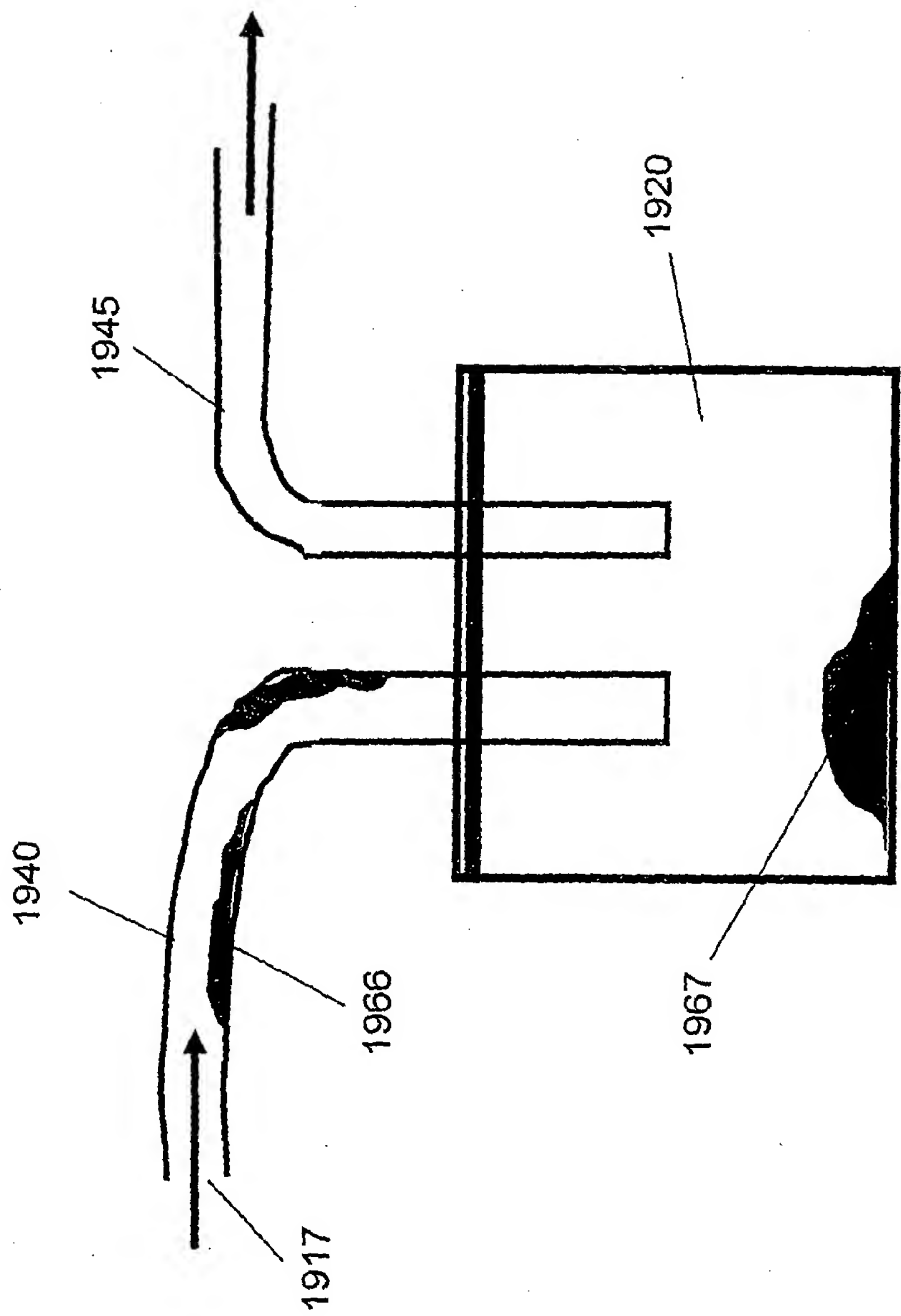


Fig. 17

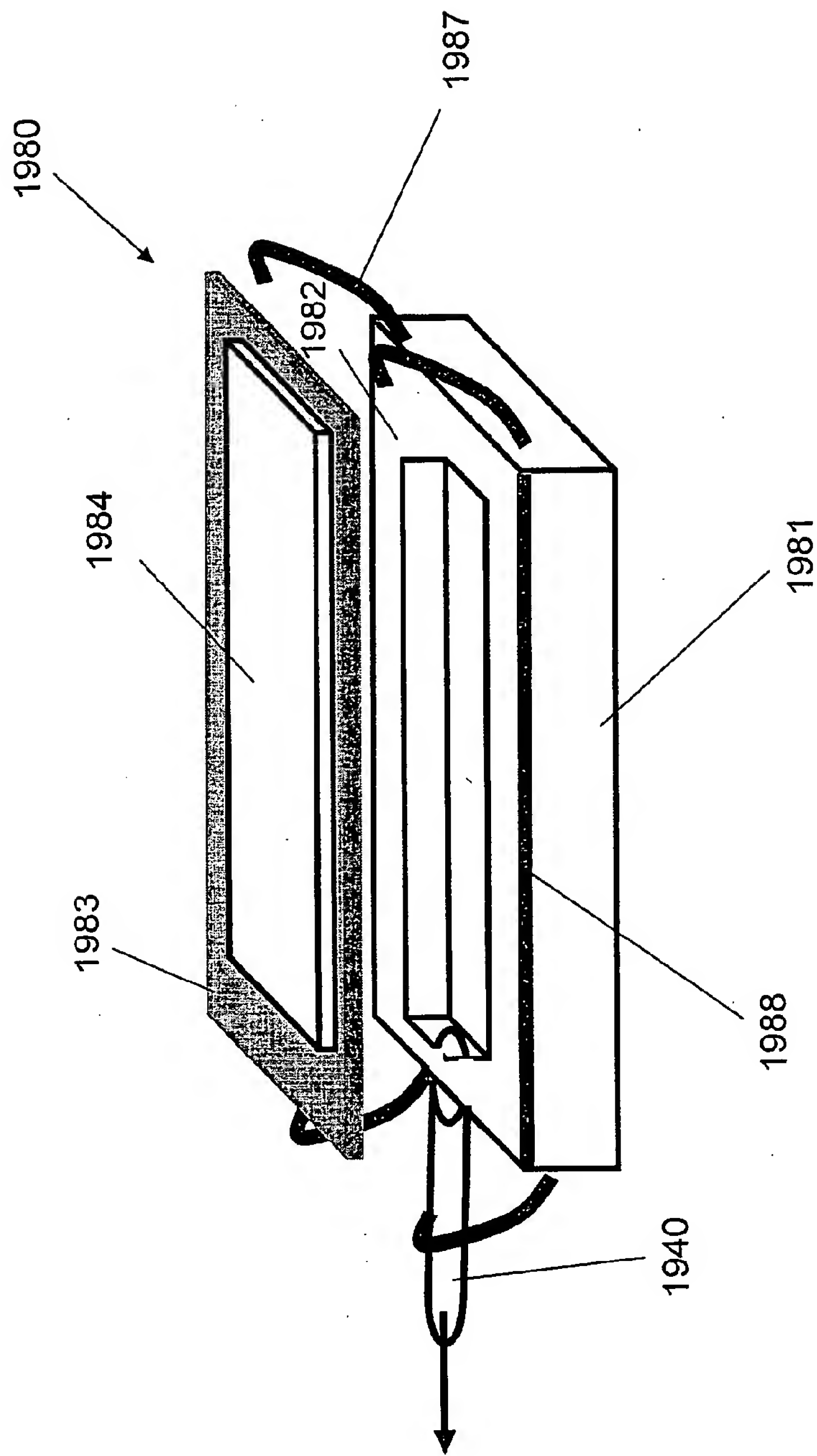


Fig. 18

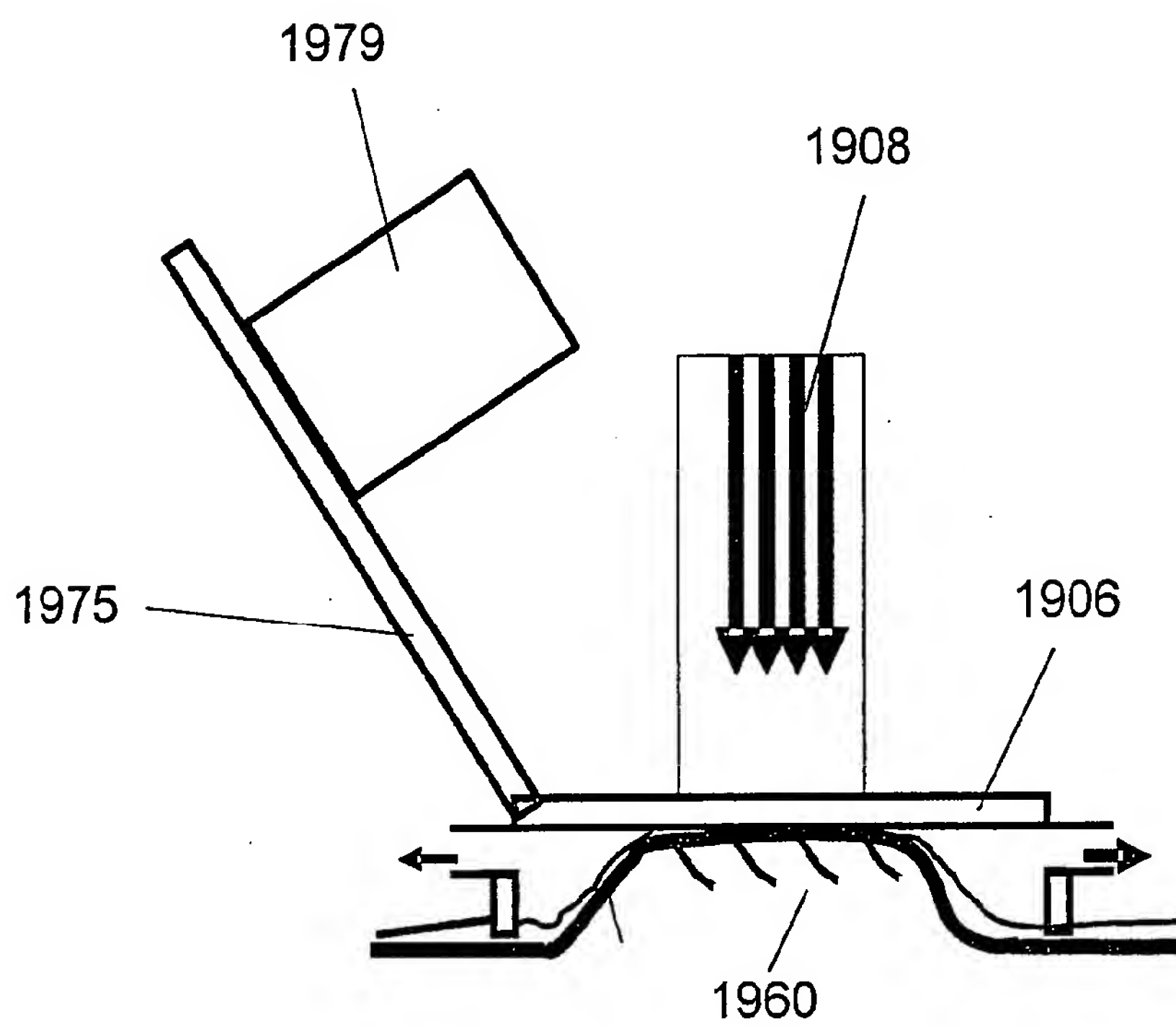


Fig. 19

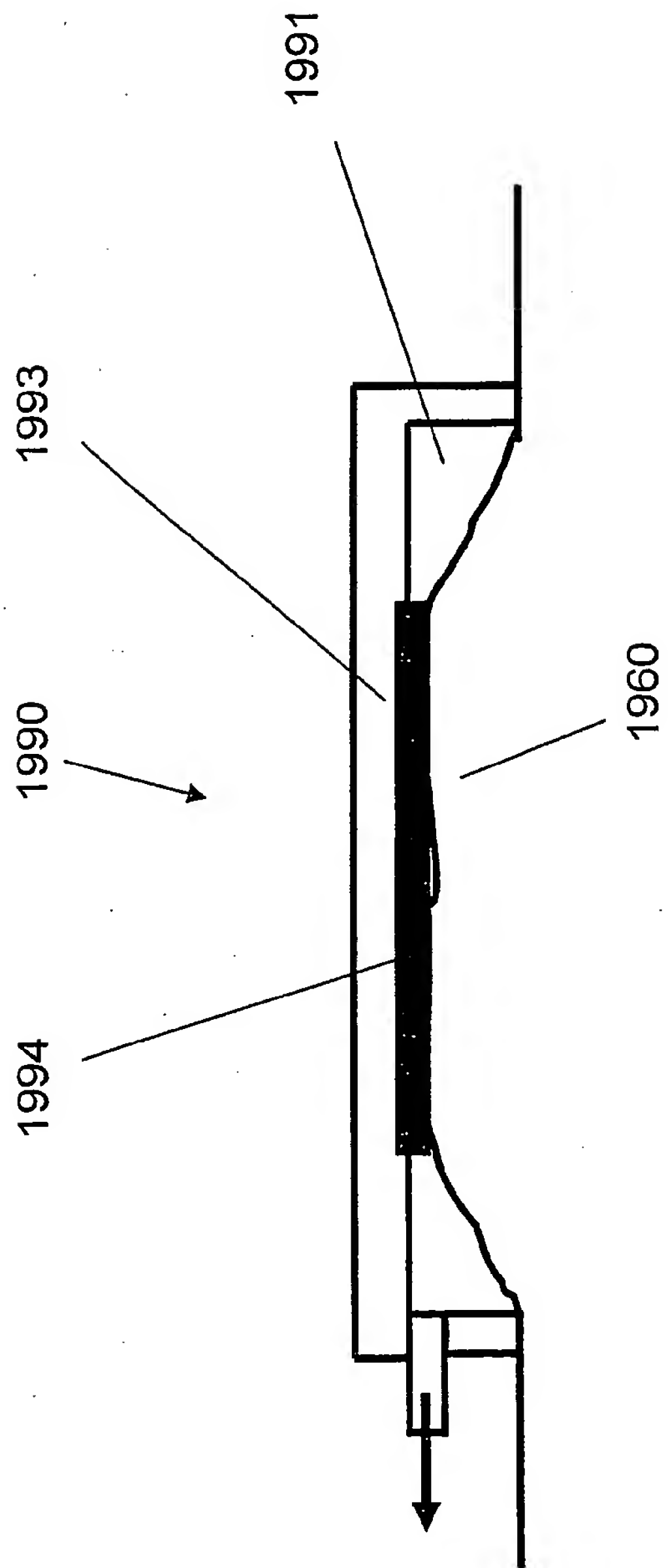


Fig. 20

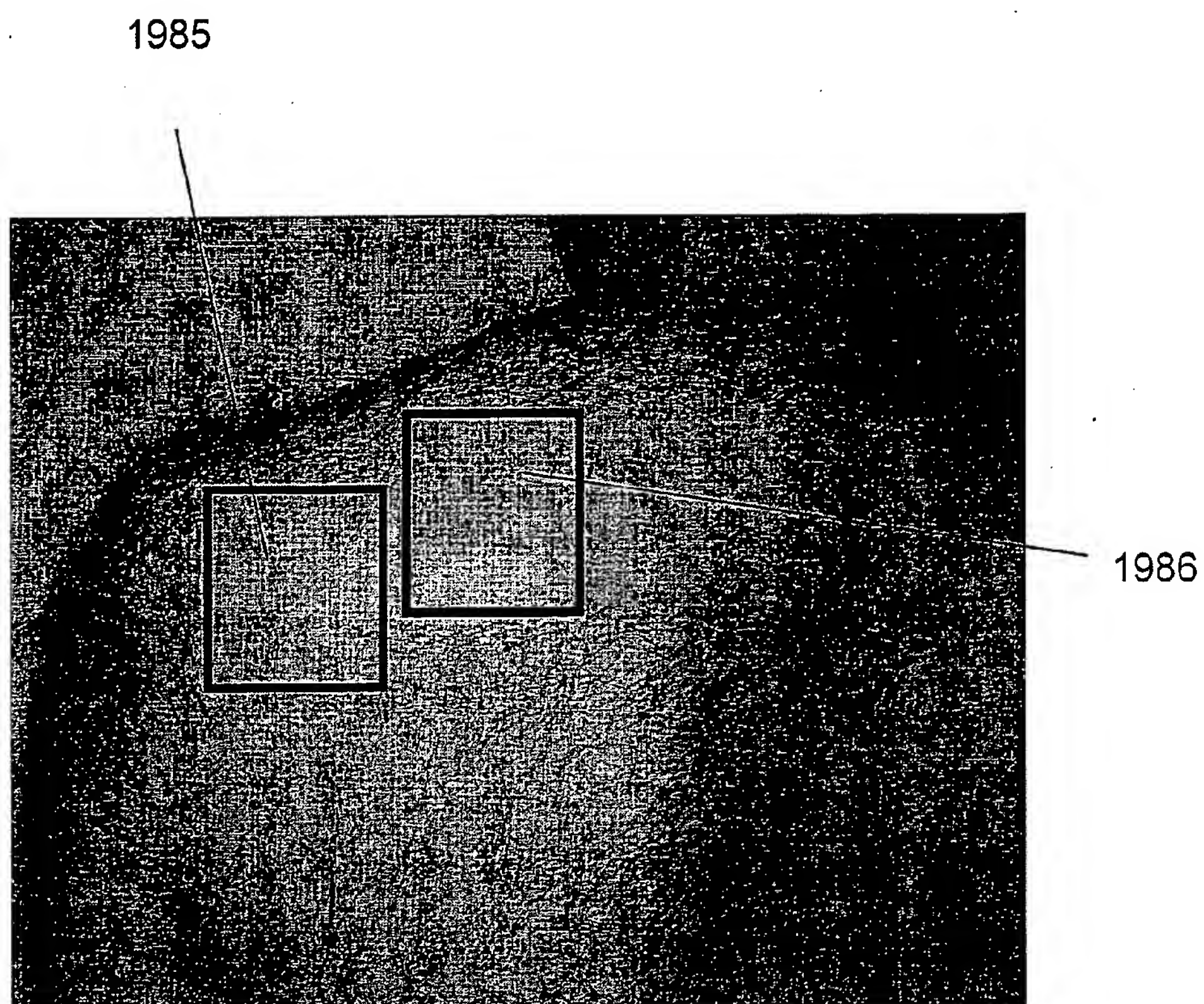


Fig. 21

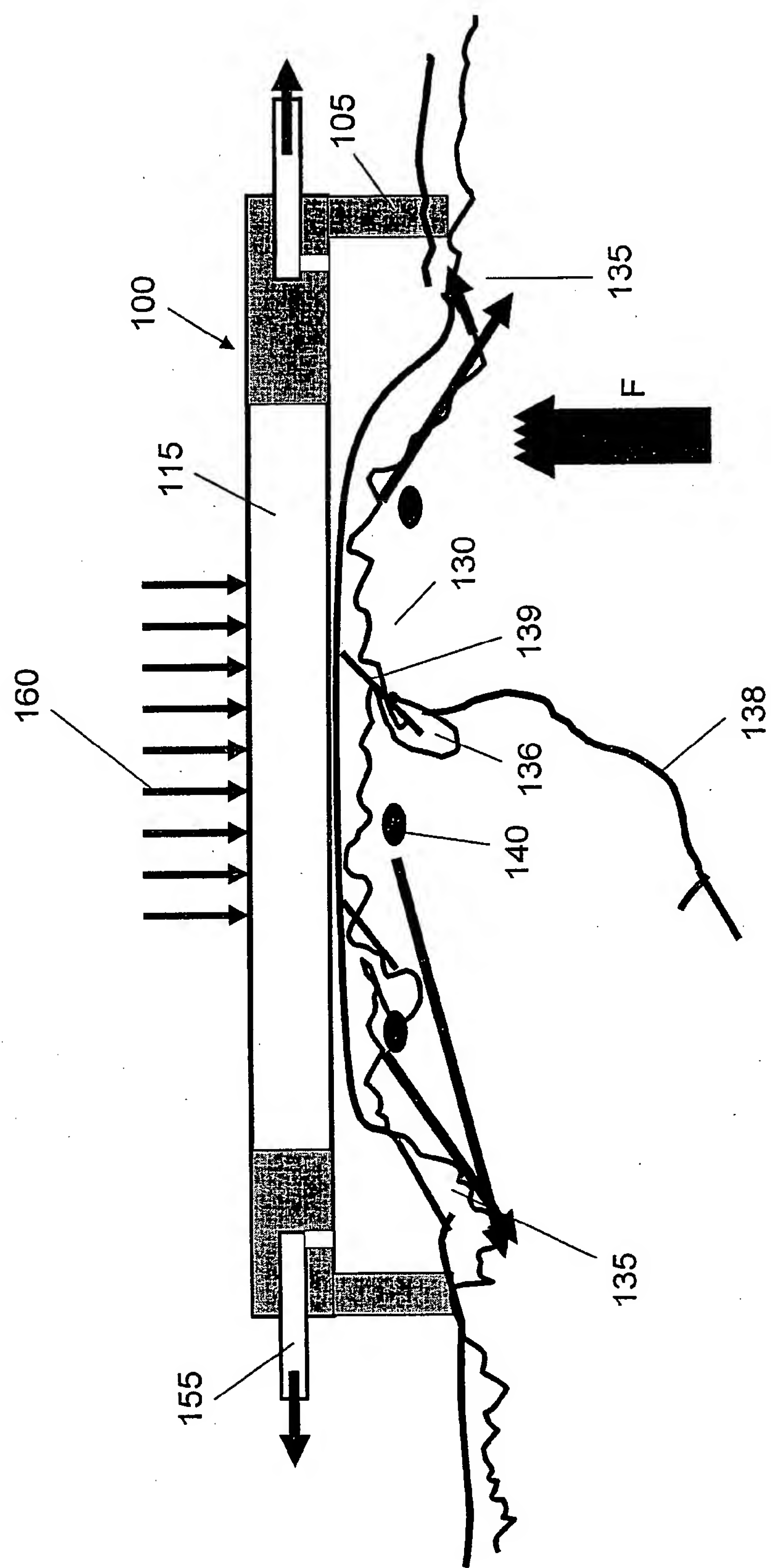


Fig. 22

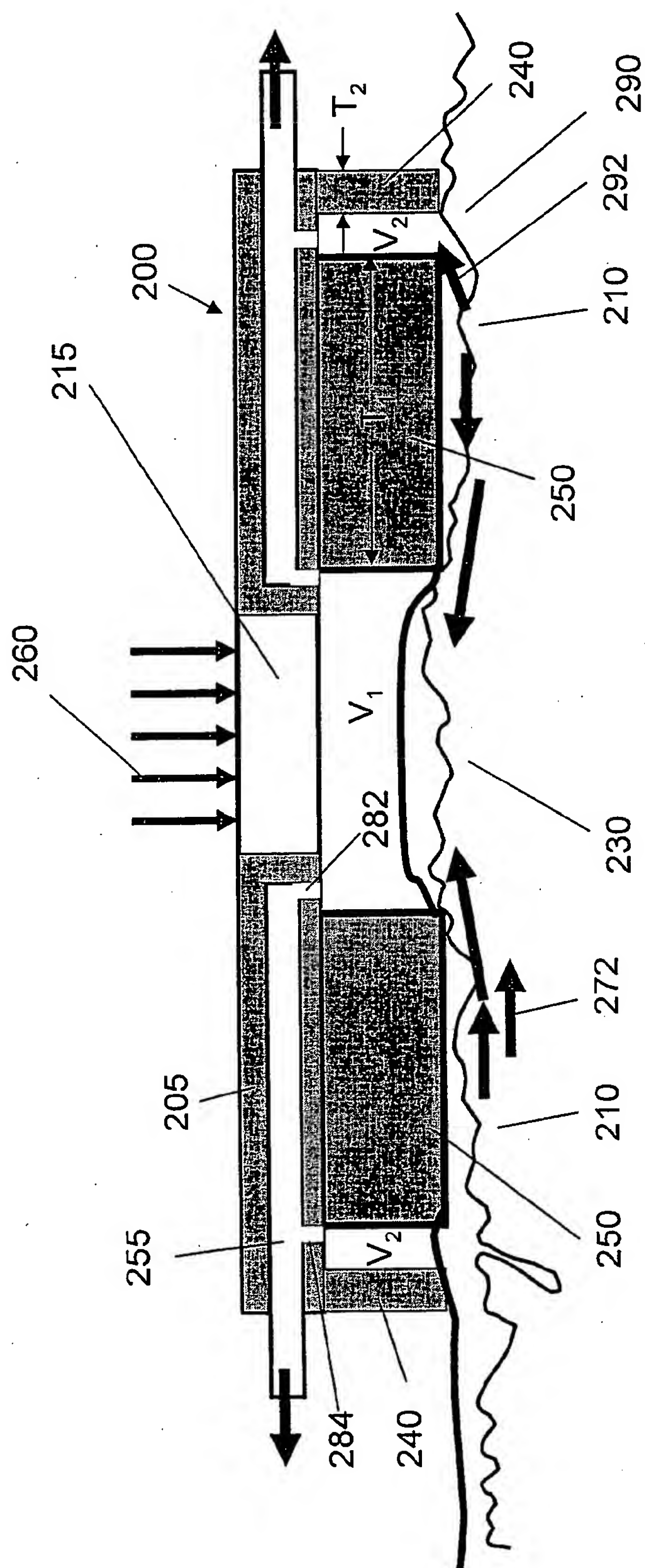


Fig. 23

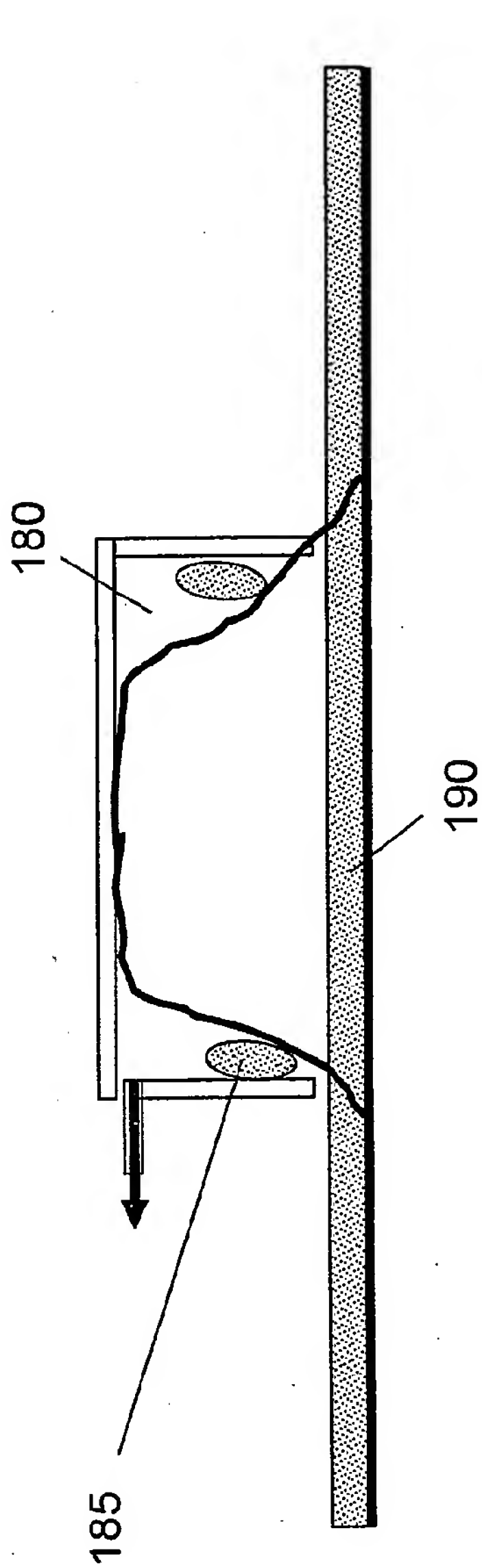


Fig. 24A

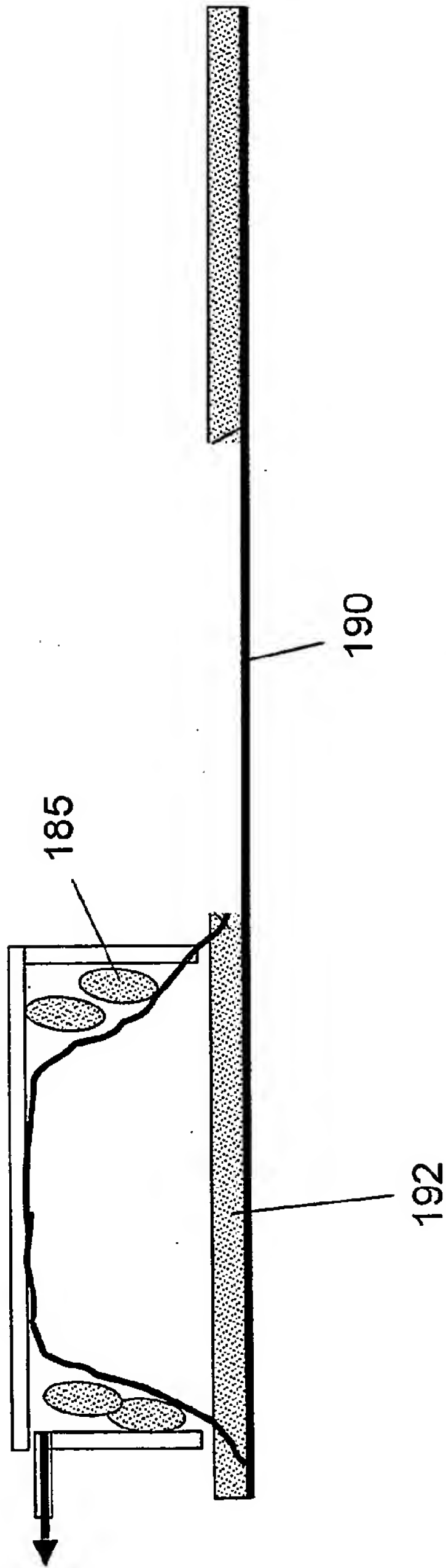


Fig. 24B

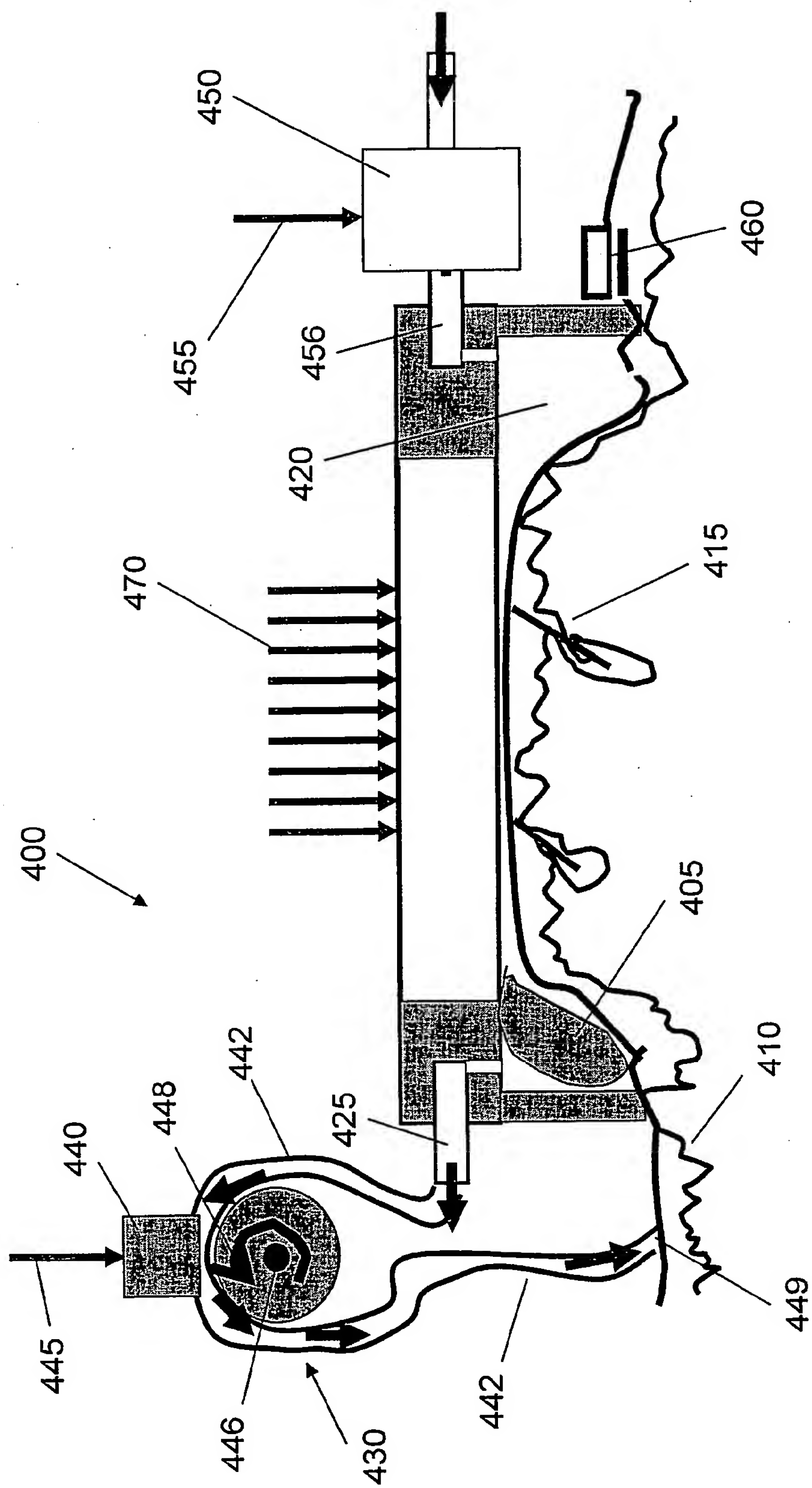
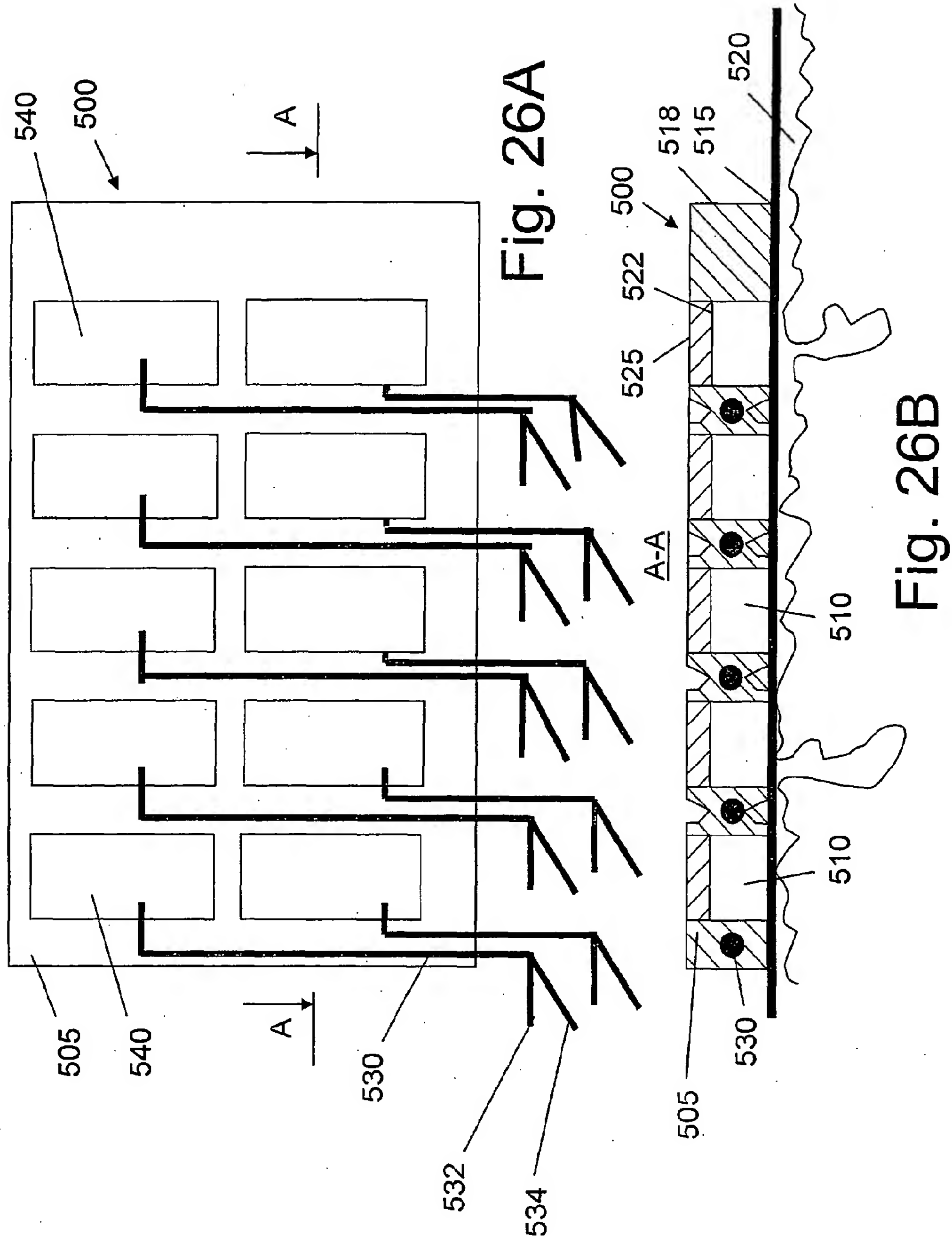


Fig. 25



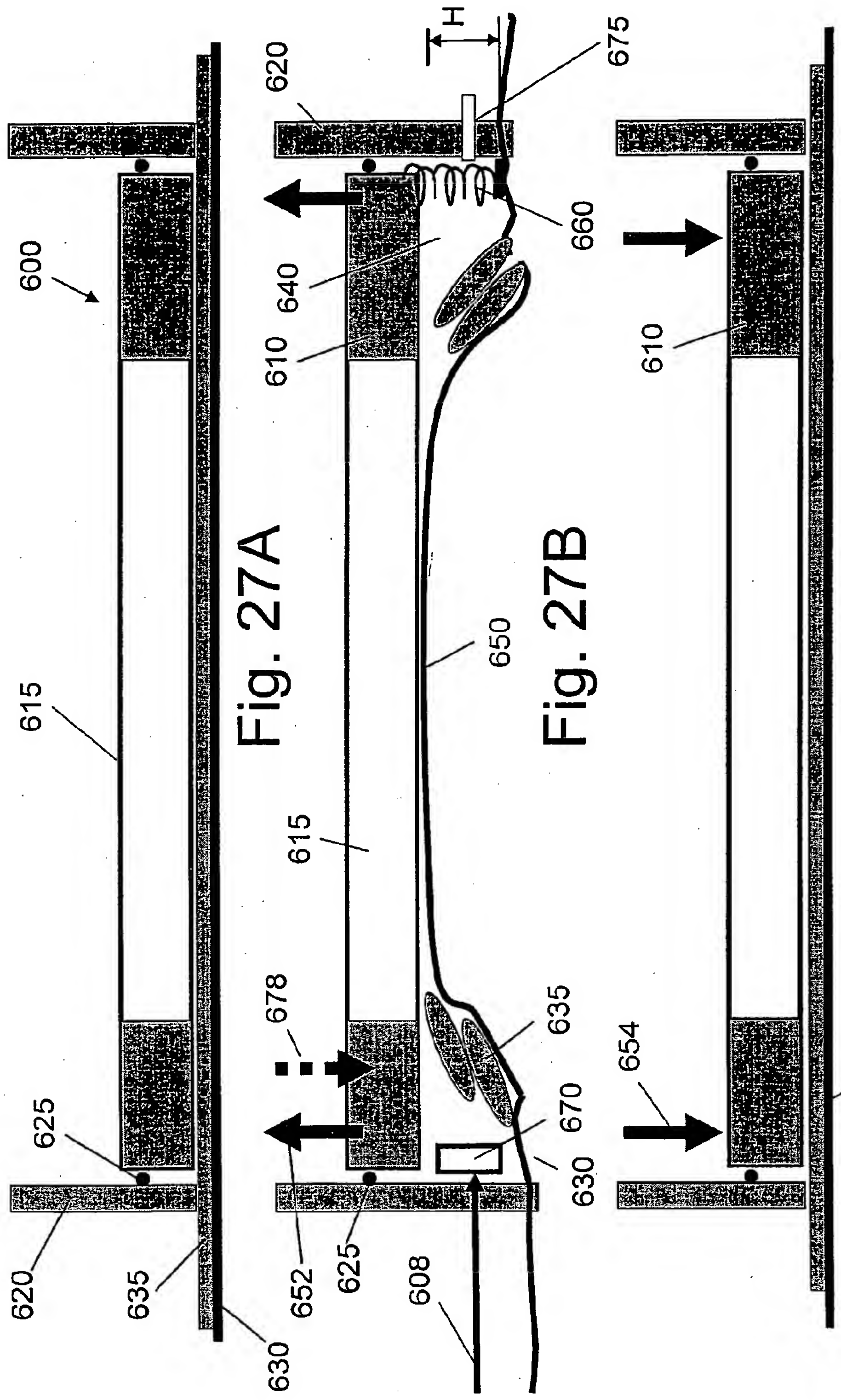


Fig. 27A

Fig. 27B

Fig. 27C

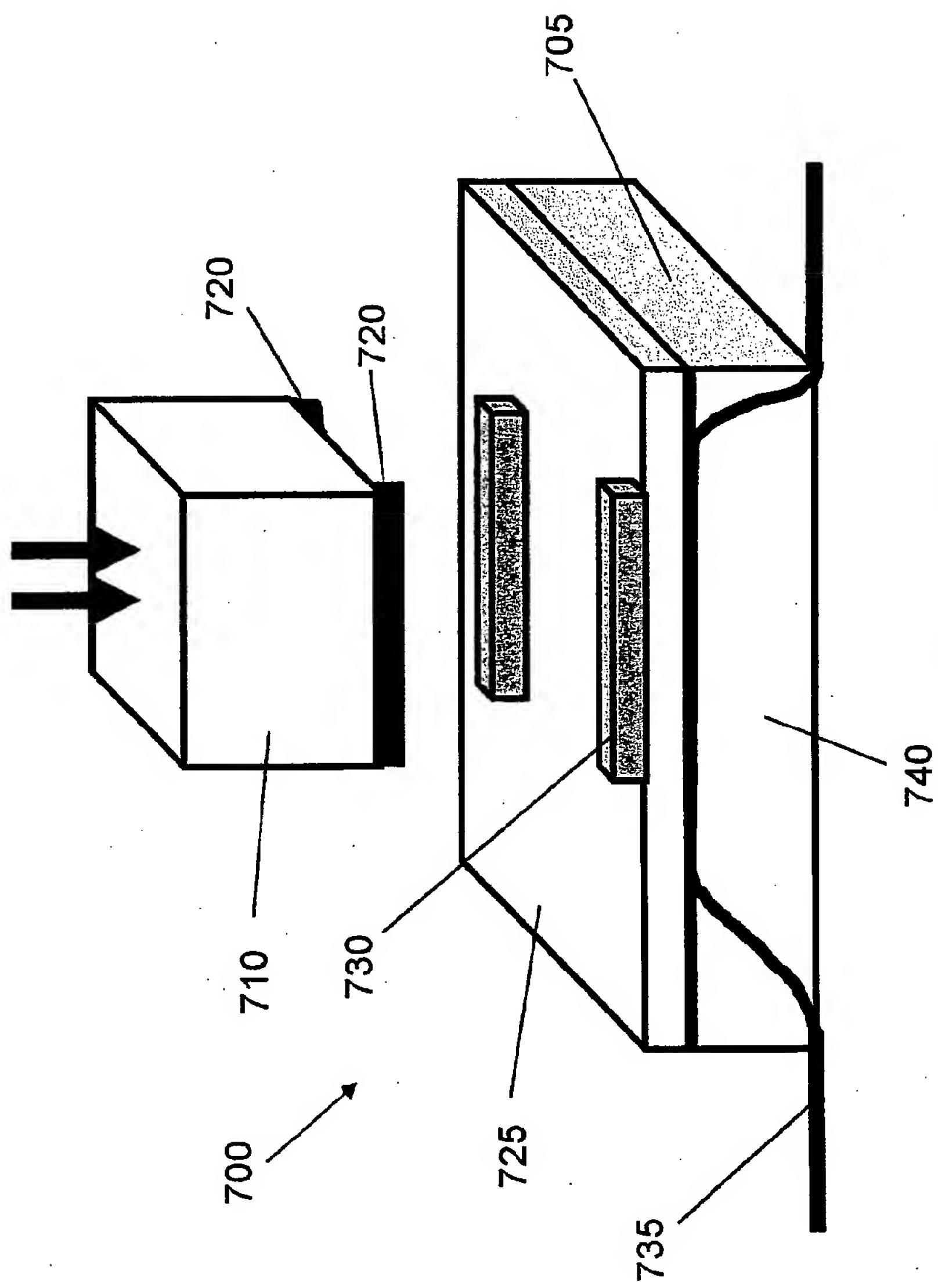


Fig. 28

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EUROPEAN SEARCH REPORT

Application Number
EP 05 00 7952

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The present search report has been drawn up for all claims			
Place of search Munich		Date of completion of the search 15 June 2005	Examiner Chopinaud, M
<div>CATEGORY OF CITED DOCUMENTS</div> <div>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</div> <div>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</div>			

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EPO FORM 1503 03.82 (P04C01)

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EP 05 00 7952

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82



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(54) **Transcutaneous laser therapy patch**

(57) The present invention relates to a low-intensity laser therapy patch consisting of a laser emitter for the transcutaneous and instant application, and which is de-

signed with an output power of the laser diode that is fixed or variable, for selecting the laser energy density for the treatment of different medical pathologies.

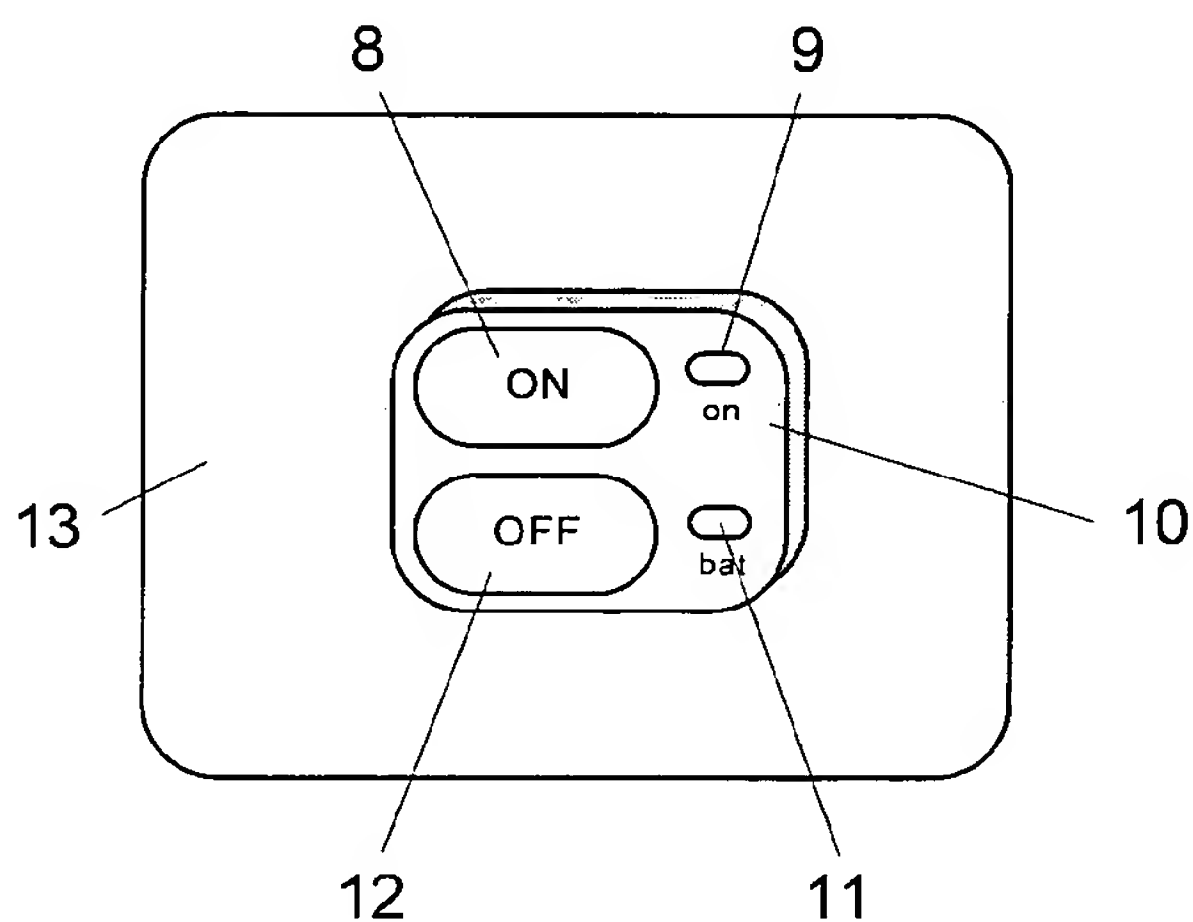


FIGURE 2

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Description

FIELD OF THE ART

5 [0001] The present invention relates to a low-intensity laser therapy apparatus for its transcutaneous and instant application in any part of the body for the treatment of different medical pathologies or aesthetic treatments.

STATE OF THE ART

10 [0002] Class IIIA, IIIB and IV low-intensity laser is applied therapeutically radiating both large body surfaces and point-based areas on small areas for the treatment of multiple diseases such as tendonitis, tendonosis, peripheral paralysis, muscle pains, epitrochleitis, epicondylitis, sprains, arthrosis of the base of the thumb, plantar heel pains, back pains, osteoporosis, contusions, herpes zoster, joint pains, muscle contractures, neuralgias, arthritis, sciatica, peri-arthritis, arthrosis, gonarthrosis, cervical arthrosis, edemas, fractures and injuries. These therapeutic applications are extended to different medical specialties: traumatology, rheumatology, dermatology, vascular, odontology and neurology (Jan Tuner and Lars Hode: Laser Therapy. Clinical practice and scientific background. Prima Books, Sweden, 2002)

15 [0003] The therapeutic effects of low-intensity laser are based on the biochemical, bioelectrical and bioenergetic effects caused by the photons in their interaction with biological structures. These effects are an increase of the production of adenosine triphosphate (ATP) and of proteins, an increase of cell proliferation and tropism, increase in microcirculation, changes in the permeability of the cell membrane, increase in endorphin and serotonin levels, increase of lymphocytes and increase of lymphatic flow.

20 [0004] The traditional technique of applying low-intensity laser therapy is carried out by means of equipment located in hospitals and clinics for a certain number of sessions and by means of short time periods. The large limitation existing in the clinical application of this technique consists of the existence of a time period from its clinical indication until its therapeutic application on the patient, and this technique not being available immediately or in the patient's home.

25 [0005] The laser energy penetrates more deeply in the skin contact technique; it is applied by means of sensors that the therapist applies manually and requires more treatment time.

30 [0006] The non-contact technique uses a higher density of laser power to compensate for the distance between the opening of the beam and the treatment area, effective treatment times are shorter and they usually automatically radiate the beam by scanning it over the tissue.

[0007] In both techniques, the action depth of the low-intensity laser therapy, combining the direct and indirect effects, can reach up to 3 cm and is in accordance with the wavelength, intensity and collimation of the beam and of the anatomical feature of the application surface.

35 [0008] The different parameters forming part of the correct selection of the dosage of low-intensity laser therapy are: the rated power of the laser (milliwatts, mW), laser power density (watts per square centimeter, W/cm²), energy (Joules, J), energy density (Joules per square centimeter, J/cm²), treatment surface area (square centimeter, cm²), distance from the laser emission point to the therapeutic target (centimeters, cm), radiation time, type of the emission: pulsating or continuous, working cycle (%), pulse repetition frequency (cycles per second or Hertz, Hz), pulse duration (nanoseconds or microseconds, ns or ms), laser wavelength (nanometer, nm) and beam divergence (degrees, °).

40 [0009] The dosage of the low-intensity laser energy is comparable to a pharmacological model in which a substance is supplied at a certain dose for the purpose of achieving a therapeutic effect.

[0010] The most widely used parameter for the laser therapy dosage is the energy density, which is quantified in Joules/cm² and uses the following formula for its calculation:

45

$$J/cm^2 = \frac{\text{Average power (W)} \times \text{Exposition time (s)}}{\text{Surface area (cm}^2\text{)}}$$

50

55 [0011] There is a laser energy dosage for the treatment of different pathologies according to the previously mentioned parameters based on the therapeutic experience of years of using this technique. For example, the following are the energy density dose for lower back pains (6 J/cm²), peri-arthritis (6 J/cm²), gonarthrosis (4 J/cm²), epicondylitis (3 J/cm²), sprain (4 J/cm²), carpal tunnel syndrome (4 J/cm²). The dosage based on energy density generally ranges from 1 J/cm²

to 99 J/cm².

[0012] Laser therapy equipment today is carried out in solid state or by means of semiconductor laser diodes. High-intensity light emitting diodes (LED) have reduced this technology, which have allowed the use of radiation with a diagnostic target of the laser in small or point-based areas such as in Doppler laser equipment, laser oximetry or laser spectroscopy.

[0013] The permanent or transient application of different types of therapeutic patches is used in the treatment of different diseases, for example: patches with medicinal products (US 2004097864), (US 6143320), (US 5154182), (US 2004043062), (JP 2002121136), (HV 0002085); electrostimulation patches; iontophoresis patches (MXP A01007996), (US 2002183685), (KR 2002013249), (US 6424862); heat-generating patches (US 2004097864); magnetotherapy patches (US 6344021), (US 3943912), (US 4587956), (US 5312321), (US 5707333). However, there are no therapeutic low-intensity laser patches.

EXPLANATION OF THE INVENTION

[0014] The present invention relates to a laser therapy patch for its transcutaneous application, applied instantly, having automatic operation and being used at home.

[0015] The laser therapy patch consists of a power supply or battery, a control circuit supervising functioning and activating the laser diode which generates a visible light or infrared laser beam.

[0016] The dose is administered instantly and automatically by means of the patient's activating an "on" button and the deactivation by an "off" button (although both functions can be carried out by a single "on/off" button according to the prior art and for the purpose of simplifying and reducing space).

[0017] The laser patch is placed transcutaneously and all the parameters forming the laser energy dosage are kept constant with the exception of the exposure time, which is variable, whereby a different energy density is generated for each disease.

[0018] With the laser patch, the laser energy dosage applied in each treatment according to its pathology is based on the fact that the parameters for calculating the energy density (J/cm²), mean power (W), energy (J) and the treatment surface area (cm²) remain steady, changing the exposure time according to the energy dose (J) indicated for each treatment.

[0019] Based on the foregoing, a different energy density is obtained for each clinical situation according to the following formula:

$$\text{Time} = \frac{\text{Dose per Surface}}{\text{Mean power}}$$

[0020] The mean power is calculated as follows:

$$\text{Mean power (Wm)} = Wp \times Tp \times F$$

[0021] Where Wm is the mean power (W), Wp is the peak power (W), Tp is the pulse duration (ns or ms) and F is the pulse frequency (Hz).

[0022] In the most simplified type, the considered power will be the maximum power of the laser diode given that a pulse working regimen is not applied, its functioning being continuous and therefore the mean power will be equal to the maximum power of the laser diode.

$$\text{Time (s)} = \frac{\text{Energy (J)} \times \text{Surface (cm}^2\text{)}}{\text{Mean power (W)}}$$

[0023] The advantages of this type of application of laser therapy are: ability to be reused by the patient for an undetermined number of sessions (the battery can be replaced), local therapeutic actions, non-invasive and painless technique, transcutaneous placement, immediate and instant application, non-pharmacological therapeutic agents, offering multiple pathologies for treatment, portable application (it is not necessary to go to a clinic or hospital to apply it), technique that is complementary or alternative to traditional therapy, very simple activation and automatic operation, low consumption and low cost. Since the laser is located in the part in contact with the skin and the upper part is made of an opaque material, it is not necessary to wear glasses for its therapeutic use.

DESCRIPTION OF THE DRAWINGS

[0024]

Figure 1 shows a circuit block diagram of the transcutaneous laser therapy patch. It shows the battery or power supply (1), on-off position switches (2 and 3), control circuit (7), operating indicator (4), low battery indicator (5) and laser emitter (6).

Figure 2 shows an upper view of the laser therapy patch, showing the "on" button (8) for the activation of the laser once positioned in the place to treat, the "off" button (12) for deactivating the laser, the operating indicator (9) notifying that the laser is on, the low battery indicator (11) notifying that the battery needs to be replaced and a battery cover (10) for accessing the battery compartment to replace it.

Figure 3 shows a lower view of the laser therapy patch, showing the laser output opening (14) and adhesive (15).

Figure 4 shows a cross-section view of the laser therapy patch, showing the "on/off" buttons (16), operating and low battery indicators (18), the battery (17), adhesive (22), a diode or laser diode array or laser emitter (21) including the optics for distributing the beam, an opening (20) where the laser diode beam exits and a control circuit (19) for controlling and exciting the laser diode.

Figure 5 shows a replaceable adhesive system for holding the laser therapy patch to the surface of the body with its central part (23) and peripheral part (24).

EMBODIMENT

[0025] The laser therapy patch (Figure 1) consists of a battery or power supply (1 and 18), a control circuit (2 and 19), diode or diode array or laser emitter (6 and 21) and a changeable adhesive system (13 and 15).

[0026] The optical system is located in the central lower part (Figure 3) and is formed by an opening (14 and 20) which may have a lens and a laser diode or diode array.

[0027] The laser diode or diode array generates a visible light or infrared laser beam. The output power of the laser diode or diode array will depend of the area to be treated and will therefore be treated according to its class. The laser diode or diode array will be excited from the control circuit.

[0028] The control circuit continuously supervises the correct operation of each of the components to assure the output power of the laser diode and for prevent overheating or malfunction. The energy for feeding the control circuit and therefore the laser diode or diode array is powered by the battery although a feed input can be provided from an external feeder or power supply.

[0029] The lower part of the patch (Figure 3) contains an opening (14) in its central part from where the laser radiation is emitted. The dimensions of said opening will be suitable for the surface area to be treated.

[0030] The "on" and "off" buttons (16) (or just one "on/off" button for simplifying and reducing space) are located in the upper part of the laser patch (Figure 4) to control the start of treatment and for the interruption thereof, and operating and low battery indicators (17).

[0031] An adhesive system (Figure 5) allows maintaining the patch on the surface of the body and consists of a central dome part (23) covering the patch of a transparent and flexible material and an adhesive peripheral part (24) coated with a coating paper.

[0032] The present invention is additionally illustrated by means of the following example of the treatment parameters,

which do not aim to be limiting of its scope.

Example: Treatment of Epicondylitis

[0033] Therapeutic target: To administer an energy density of 2 J/cm².

[0034] According to formula:

$$\text{Time} = \frac{2 \text{ J/cm}^2 \times 2.25 \text{ cm}^2}{5 \times 10^{-3} \text{ W}} = 900 \text{ s} = 15 \text{ min}$$

Energy density (2 J/cm²)
Power of the diode (5 mW)
Treatment surface (2.25 cm²)
Radiation time = 15 minutes

INDUSTRIAL APPLICATION

[0035] The invention can be applied in the electromedicine, physiotherapy, rehabilitation, aesthetics, odontology and veterinary fields.

Claims

1. A transcutaneous laser therapy patch **characterized in that** it consists of a power supply or battery (1) activating an operating control circuit (7 and 19) exciting a semiconductor diode or diode array (6 and 21) or another laser emitter for its instant transcutaneous application with automatic functioning by means of an independent adhesive system (13, 15, 23 and 24).
2. A transcutaneous laser therapy patch according to claim 1, **characterized in that** the laser used is a class IIIA or IIIB low-intensity laser and can be formed by one or several laser diodes or diode array, or other laser emitters (6 and 21) acting simultaneously or sequentially and with continuous or pulsating emission in any of its combinations.
3. A transcutaneous laser therapy patch, according to claims 1 and 2, **characterized in that** it contains a control circuit powered by a battery or power supply (1 and 18), exciting the laser emitter and supervising and controlling the parameters of the laser energy to be applied in different therapeutic treatments. The control circuit supervises the power and prevents the overheating or malfunction of the system.
4. A transcutaneous laser therapy patch, according to claims 1 and 3, **characterized in that** the control system consists of an activation and deactivation button for starting and ending the treatment (2, 3, 4, 8, 9, 12 and 16) as well as the operating state of the battery or power supply (5 and 11).
5. A transcutaneous laser therapy patch according to the previous claims, **characterized in that** its external configuration can vary in design, shape and size, as well as the configuration of the laser equipment and the skin adherence system according to the surface areas to be treated.
6. A transcutaneous laser therapy patch according to the previous claims, **characterized in that** it has an industrial application in the electromedicine, physiotherapy, rehabilitation, aesthetic, odontology and veterinary fields, with advantages of use by the patient immediately and instantly, non-invasive techniques and easy to use and operate.

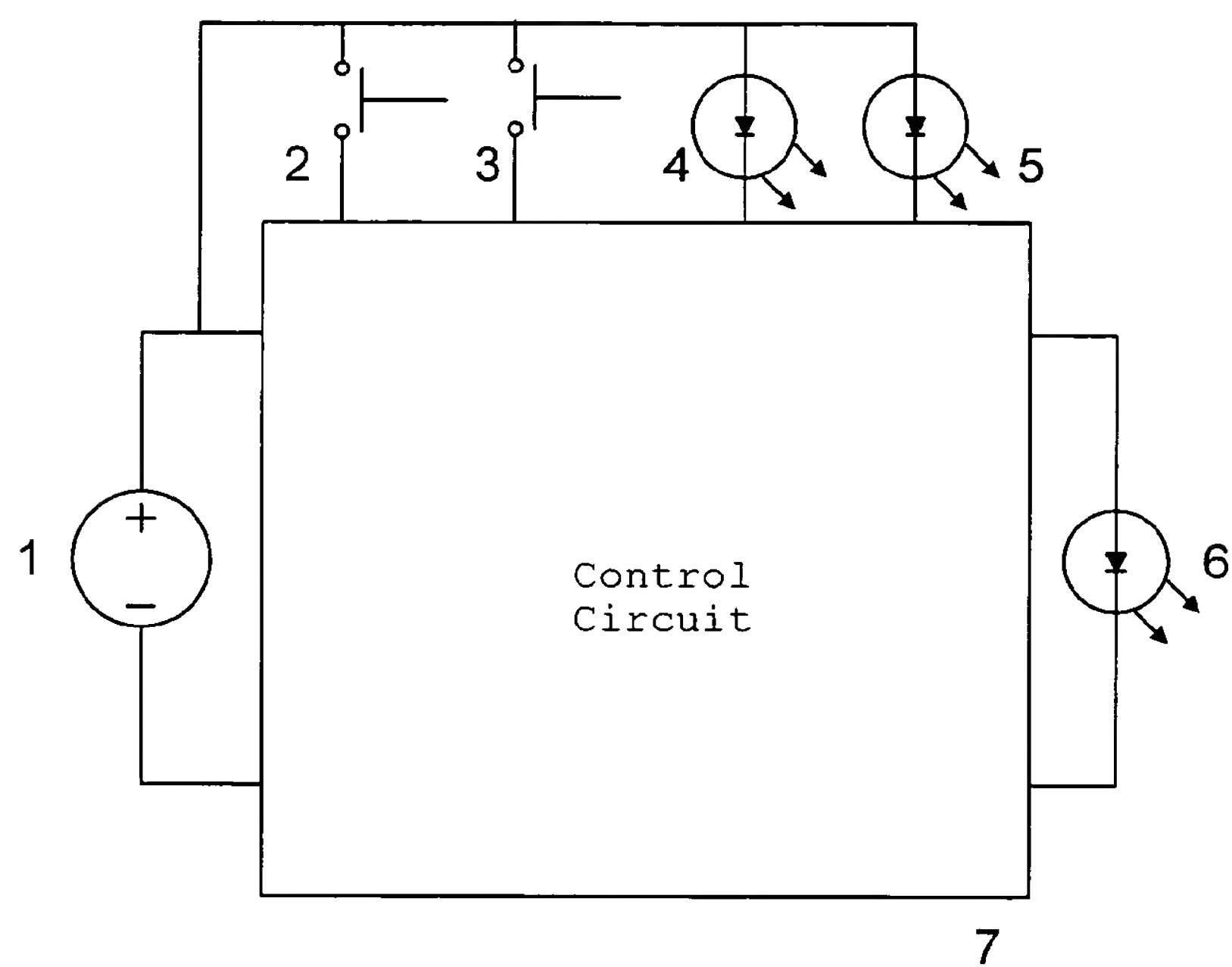


FIGURE 1

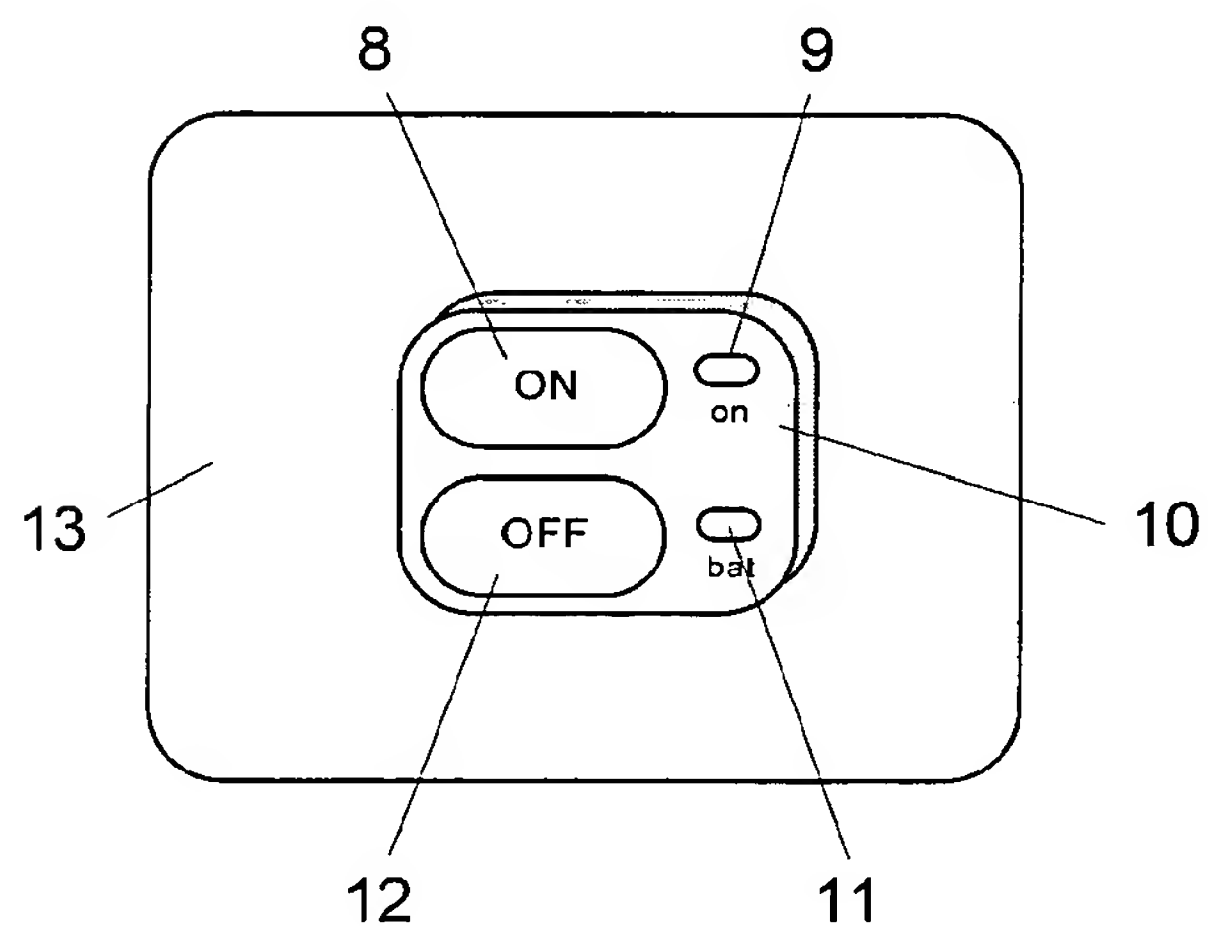


FIGURE 2

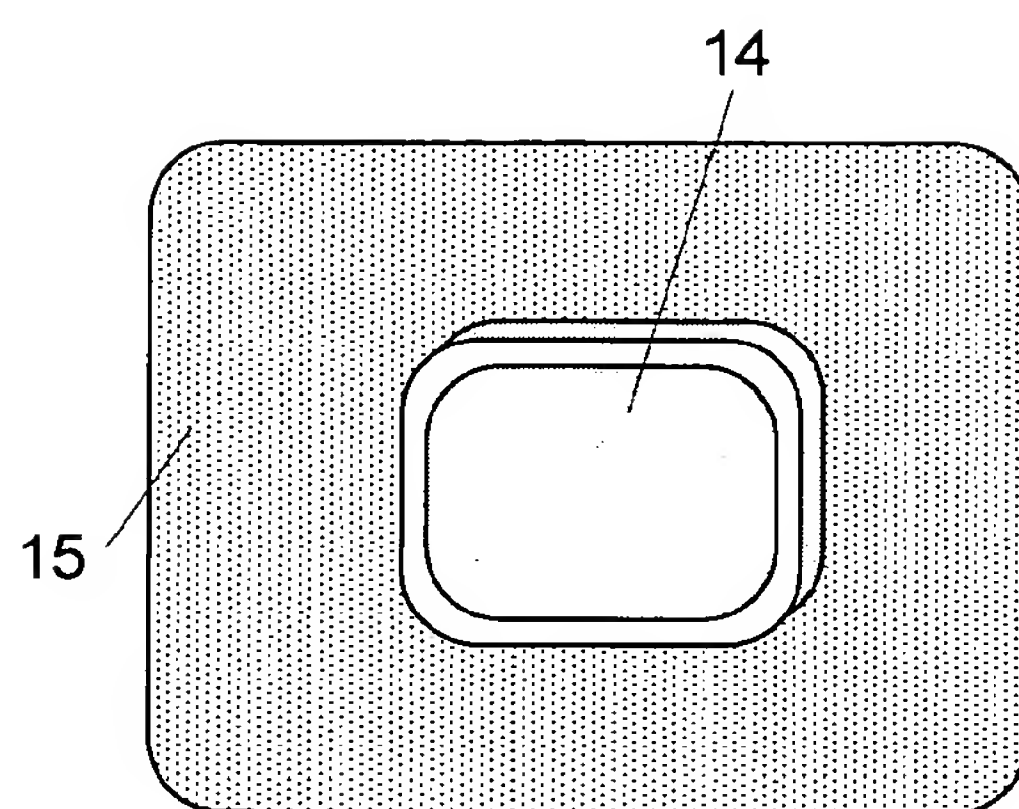


FIGURE 3

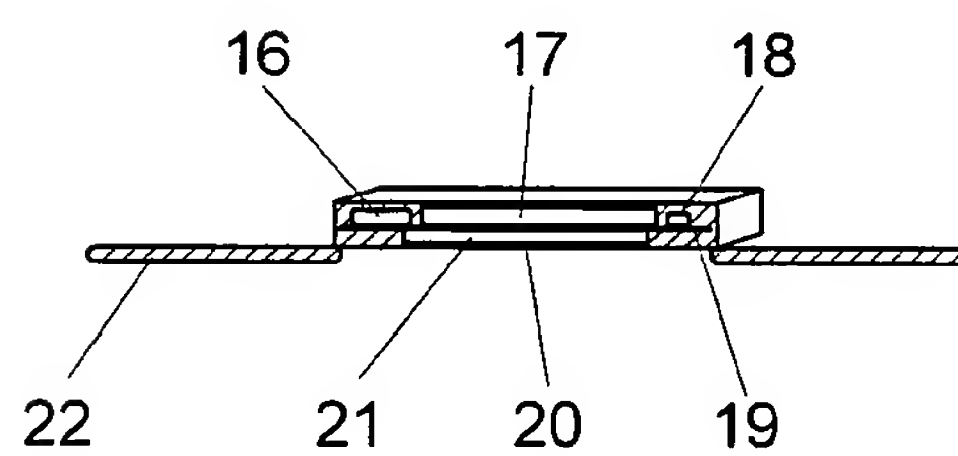


FIGURE 4

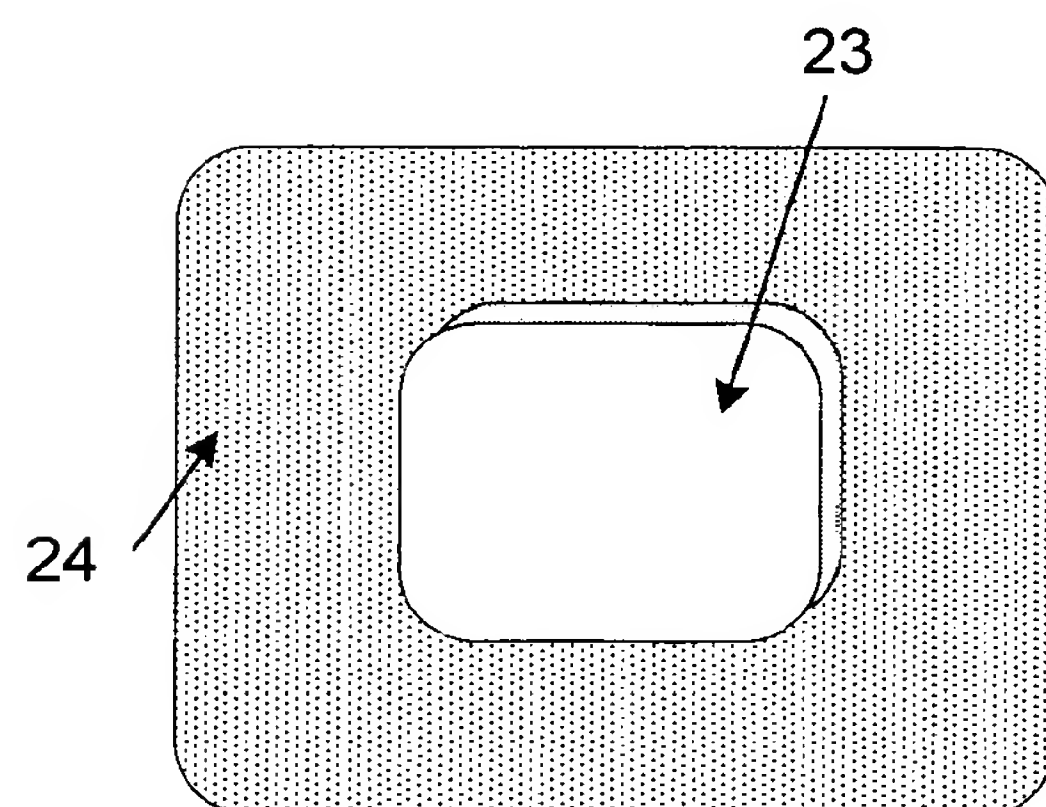


FIGURE 5



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Application Number
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Place of search The Hague		Date of completion of the search 24 July 2007	Examiner Petter, Erwin
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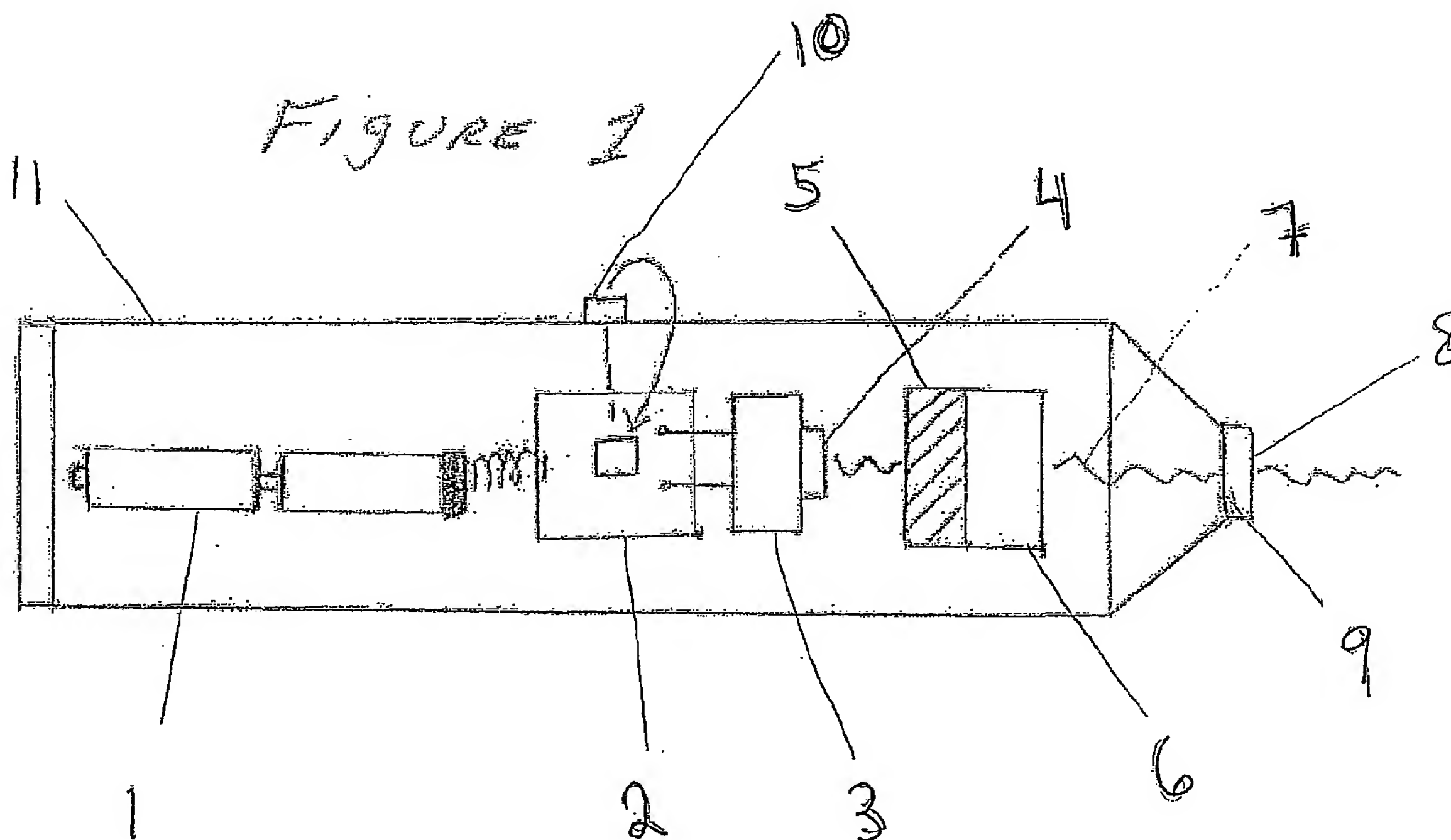
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(54) **Device and method for treating musculo-skeletal injury and pain by application of laser light therapy**

(57) A laser therapy device and method of treatment for treating musculo-skeletal pain. The device and treat-

ment employ a composite laser beam comprised of multiple frequencies of laser energy.



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Description

CROSS-REFERENCE TO RELATED APPLICATION:

[0001] This application for utility patent claims priority from Provisional Patent Application 60/746,668, filed on May 8, 2006, entitled: Device and Method for Treating Musculo-Skeletal Injury and Pain by Application of Laser Light Therapy.

FIELD OF INVENTION:

[0002] The present invention lies in the field of medical devices. In particular, it relates to the treatment by means of laser light of musculo-skeletal pain and wounds.

BACKGROUND OF THE INVENTION:

[0003] Laser Light Therapy is well known in the treatment of a wide variety of medical conditions whereby the laser emits light at certain specific bio-effective frequencies. In various applications, it is used to treat musculo-skeletal pain caused by injury or chronic and acute conditions. A non-exhaustive list of the conditions treated by Laser Light Therapy includes whiplash, arthritis, migraine, lower back pain, tendonitis, carpal tunnel syndrome, tennis elbow, golfer's elbow, strains, sprains, knee, neuropathy, ankle and foot pain, TMJ, and soft tissue injuries. The therapy is also useful in treating and promoting wound healing.

[0004] Depending on the nature and extent of the treated injury, the effects of Laser Light Therapy may be either curative or palliative. Where soft tissue injury is involved, such as in the case of sprains or strains, the device appears to promote direct healing of the injured tissue. If the injury is structural as in the case of a torn ligament or bone fracture, the device provides palliative relief and may be used in conjunction with other treatments.

[0005] Laser light consists of discrete coherent light of a wavelength from a narrow spectrum of electromagnetic radiation ("EMR"). In general it is amplified EMR that is monochromatic, collimated, polarized and concentrated in a relatively defined location or spot. Low Level Lasers are considered to be lasers varying in power intensity from 1 mW to 500 mW and are commonly used in therapy. The properties of laser light in general are such that it penetrates the surface of the skin without, or when desired with only limited, associated heating. Laser light is well known to possess and direct bio-stimulating energy to the cells of the body which, in turn, facilitates and enhances the body's own healing and pain regulating mechanisms.

[0006] Laser Light Therapy appears to be an effective treatment because of its ability to enhance the maintenance or restoration of biological systems to proper conditions of homeostasis and its ability to initiate or amplify the body's own regenerative systems. Injury or other chronic conditions may have a deleterious affect on cel-

lular systems and thereby compromise the cell's ability to regulate its functioning or to effect repairs where tissue has been damaged. Where cell membranes have been damaged, laser light therapy enhances receptor-mediated movement across the cell membrane. Thus it has a positive effect on the cell's ability to maintain or restore proper function, repair of the cell's enzyme systems and re-establish the proper balance of proteins, ions or carbohydrates to allow the cell to function normally. Often, the addition of energy to the cell system can restore proper function and balance as the cell is re-stabilized and homeostasis is restored.

[0007] In laser therapy, photonic energy is emitted from a laser source. The energy, in the form of photons, is absorbed by photo acceptor sites on the cell membrane. This in turn triggers the cell's biochemical pathways which initiate the transmission of a variety of signals initiating, inhibiting or accelerating a variety of biological processes. These processes include inflammation reactions, cell growth or pain blocking. Furthermore, photonic energy is known to promote and optimize antiinflammatory and immuno-stimulative effects.

[0008] In general, the significant biological effects of laser light are known to include cell growth stimulation and cell regeneration which positively affect connective tissue, tendons, bone, muscles and nerves. Laser light therapy promotes revascularization of damaged or injured tissue leading to positive therapeutic effect. Further, laser light therapy is known to improve microcirculation in injured or damaged tissue thereby relieving, for example, edemas, and facilitating the healing of in treating torn or damaged muscle tissue. It further acts to inhibit inflammation of afflicted areas by inhibiting the ability of leukocytes to trigger increasing inflammation responses. It is also known to reduce fibrous tissue formed in response to injury.

[0009] At the cellular level, Laser Light Therapy is also well-known to increase the levels of adenosine triphosphate (ATP) produced by the mitochondria of the cell. One effect of laser light is to promote and stimulate cytochromes, including porphyrin, to produce singlet oxygen during the creation of ATP. ATP, in turn, plays a critical role in transporting energy within the body's cells and tissue and thus greater levels of ATP act to stimulate higher levels of cellular activity. Increased ATP production promotes increased levels of various growth factors and higher levels of protein synthesis, which are key for cellular repair and functioning.

[0010] Under the stimulation of laser light energy, greater degrees of cell proliferation have been observed. Other beneficial effects include increased levels of endorphin release leading to pain relief, both acute and chronic. Increased lymphocytic activity leading to a stronger immune response is also observed. Another well known beneficial effect of laser therapy is the promotion of revascularization of the blood and lymph vessels in response to therapy. This is particularly useful in treating edema and contusions related to injury or trau-

ma.

[0011] Presently, lasers of particular wavelengths are known in the prior art. None, however, disclose the art of a composite beam comprised of laser energy emitted at wavelengths of 532 nm, 805 nm and 1064 nm which this device in its preferred embodiment does. An example of this is Patent 5,464,436 which uses laser light within the range of 800-870 nm, more preferentially 830 nm, to treat a variety of musculo-skeletal injuries and conditions. Other therapeutic devices used for treating injuries and musculo-skeletal pain include laser emitting light at frequencies in the range of 635 nm at approximately 5 mW of power. While relatively powerful lasers emitting light at wavelengths of 532 nm are used by surgeons in the removal of tattoos and by dentists for bleaching or whitening teeth, the use of such frequencies is little known in the treatment of musculo-skeletal pain and injury. An example of one patent that does employ a similar frequency is U.S. Patent # 6,582,454 to Yayama. While Yayama does use a beam emitted at a frequency of 530 nm in connection with other beams, none of the other beams include frequencies of the infrared spectrum. Laser light at that frequency is known to be readily absorbed by hemoglobin. Therefore it is used in ablating blood vessels and treating other cosmetic skin conditions caused by blood vessels such as port wine stains. It is further known to readily penetrate the skin.

[0012] Furthermore, in lasers that are used to treat musculo-skeletal pain, the emitted therapeutic light is typically of one wavelength only, typically ranging from 635 nm to 980 nm. While multi-diode lasers may be used, the diodes usually emit identical frequencies of EMR and thus merely increase the energy deposited without varying the spectrum of the treating light source. Where multiple-diode lasers have been employed that emit different wavelengths, such as in Patent 4,669,839, only one wavelength has been selected for its therapeutic quality and effect. A second wavelength is typically used as a guide beam to assist in directing the therapeutic beam. When multiple frequencies are used to treat musculo-skeletal conditions as in the '454 Patent, the frequencies have not included similar combinations of frequencies as disclosed herein and in fact differ in their characteristics. The instant device for example includes infrared wavelengths which allow greater penetration of the tissue than visible wavelengths as in the '454 Patent. Furthermore, in the instant invention, the laser beams do not intersect and then diverge as in Yayama but rather are emitted as a composite beam and this too facilitates the deeper penetration of the target tissue than Yayama. Not only does the composite beam penetrate more deeply than Yayama without diverging, each component beam of the composite beam simultaneously strikes the same target tissue and from the same angle. Furthermore, in at least certain embodiments of this device, at least two (2) composite beams form an octave, here the 532 nm beam and the 1064 nm beam or at least approximate an octave.

Summary of the Invention:

[0013] The present invention uses multiple beams of different frequencies to provide improved beneficial therapeutic and palliative effects of laser therapy. Preferably, at least one of the multiple frequencies should fall within the 532 nm range. Heretofore the therapeutic effects on musculo-skeletal conditions of lower frequency lasers in the 532 nm range has gone unappreciated. Indeed there is currently no therapeutic device or treatment practiced employing the use of a laser beam emitting EMR at that frequency. Thus one aspect of the present invention is the use of EMR at the heretofore unused 532 nm frequency in the treatment of musculo-skeletal injury and pain.

[0014] Further, the treatment of such conditions by a laser beam composed not of a single therapeutic frequency but from energy of different, simultaneously emitted, therapeutic wavelengths is not known or practiced. The present invention thus provides a therapeutic method and device for treating pain and tissue damage employing both features. The present invention generates a multifrequency beam reaching transcutaneously into afflicted tissue without causing significant heating and employing energy of a heretofore unused therapeutic, lower frequency in combination with energy of higher frequencies. Based upon observed treatments using the present invention, the use of a laser beam emitting a variety of frequencies as in the present invention appears to have a synergistic effects on the treatment of musculo-skeletal pain and injury.

[0015] It should be appreciated, furthermore, that use of this device is not limited to the treatment of humans. Indeed, the disclosed device should also prove useful in treating any mammals.

[0016] The present invention in one embodiment relies upon a lasing source that generates a laser beam having a frequency of 532 nm at a power of up to 65 mW. Additionally, the beam, according to one embodiment of the invention, transmits additional EMR at wavelengths of 808 nm and 1064 nm and at a combined power of no more than 435 mW but closer to 200 mW. Further the beam produced is relatively dispersed in order to minimize any associated thermal effects on the areas of the body treated. The device may be specially manufactured or adapted from preexisting commercially available devices.

[0017] It should be readily appreciated by those skilled in the art that a composite laser beam having the characteristics set forth herein may be generated by other means. For example, individual laser devices or diodes could be used to generate isolated beams which through the use of beam splitters could then be merged to form a composite laser beam. Additionally a variety of mirrors or other optics could be employed to merge multiple beams so that same could be emitted as a composite beam through a single aperture.

[0018] The specific frequencies are not considered

limitations of the device and surrounding frequencies in combination may prove equally effective. Thus, a device according to the present invention may include EMR from higher or lower frequencies around the ranges disclosed herein. EMR from the yellow bandwidth, ranging up to 594 nm, which is also known to be readily absorbed by hemoglobin, may also be included. So, too, may intermediate frequencies in the range of 808nm to 980 nm be encompassed in the device, whether emitted from a single diode or multiple diode laser. Further, frequencies in the range of 1064 nm to 1300nm may similarly be encompassed in the device.

[0019] Additionally, the power output of the laser is not considered to be a limitation, and more powerful or less powerful lasers may also be employed according to the instant invention. For example, lasers incorporating 1-5 Watt pump diodes and generating energy beams of similar frequencies may also yield similar beneficial results.

[0020] The selection of a laser beam composed of energy of lower, heretofore unused wavelengths in combination with higher frequencies has been observed to yield highly positive results in the treatment of various musculo-skeletal conditions, including but not limited to those identified above, when therapeutically applied.

[0021] In the first aspect of the method for treatment according to the invention, the health care provider diagnoses the afflicted area of the patient to determine specific treatment points associated with the condition for which relief is sought. The treatment may be applied to a wide variety of musculo-skeletal conditions and structures of the body. The present invention may beneficially treat conditions including, but not limited to, inflammation, necrosis/gangrene, hematomas, edema, contusions, strains, sprains, avulsion, ruptures, arthritis and other chronic and acute pain. In addition the treatment may be used to promote wound healing. In the treatment, Laser Light Therapy targets a array of various tissue structures of the body that may be associated with the condition. These include skin, subcutaneous tissue, mucous membranes, muscle, tendon, the vascular system, the lymph system, joints of the skeletal system, the nervous system, as well as the periosteum.

[0022] Diagnosis may employ various examination techniques including: (1) palpation of the afflicted region to determine areas of sensitivity and tenderness; (2) visual observation including regions of swelling, redness or similar; (3) viewing of x-rays, MRIs or other imaging depictions; or (4) recourse to known or determined acupuncture points, and the tracing of the peripheral nerve supply of the affected tissue to its spinal source level. The second step involves treating the patient by applying the barrel of the laser device onto the afflicted-area in an appropriate pattern and for an appropriate duration thereby applying a proper dosage of laser light. Many times, irradiating the damaged tissue will elicit a pain response from the patient, confirming the existence of pathology. Where wounds are treated, the therapy is somewhat modified in that the barrel of the laser is not directly ap-

plied to the afflicted area. The wound area is irradiated as well as the healthy tissue on the periphery. During this phase, the above outlined treatment may be repeated a number of times in response to the results observed by the health care provider and feedback from the patient. The treatment may further incorporate the application of light therapy along the peripheral nerves and concluding at the spinal segment supplying the afflicted areas. Depending on the severity of the condition and the results of initial treatment, follow up visits may be appropriate over a period of days and weeks. More specific treatment protocols that represent variations on this general treatment are described below.

Brief Description of the Drawings

[0023] Fig. 1 shows a schematic of the device according to one aspect of the present invention

[0024] Fig. 2 shows the device in operation.

Detailed Description of the Preferred Embodiments

[0025] Fig. 1 shows the device according to one aspect of the present invention. In the device as shown, a power source, 1, is connected to a 500 mw driver board, 2. While standard AAA batteries are shown, it should be readily apparent to one skilled in the art that other power sources may be employed. A standard plug-in electrical connection, for example, could also be used. The power source is used to power the driver board, 2, here a 500mW driver board. The driver board, 2, in turn powers an 808 nm pump laser diode, 3. The diode, 3, emits a beam through a microlens, 4. The resultant beam is then emitted through an NDYV04 crystal, 5, and thereafter through a KTP crystal, 6. The resultant composite laser beam is emitted through a collimating lens, 8, and then through a single aperture, 9. The resultant laser beam is comprised of laser energy emitted at approximately 532 nm, approximately 808 nm and approximately 1064 nm.

[0026] The device also incorporates a shut-off switch, 10, that allows the user to regulate the duration of the application of the composite beam and also to prevent the device from overheating and otherwise burning out the laser diode. The danger of overheating is controlled by the relatively short durations of the application. In other embodiments, the laser device may incorporate heat sinks, cooling fans or other mechanisms for regulating the thermal output of the device and controlling associated problems. The device as shown may be housed in a casing, 11, of suitable size and shape for being held in the hand of an operator.

[0027] In another embodiment of the invention the laser beam may be emitted as a pulse beam. Thus, the beam includes pulsed laser energy emitted at least at approximately 532 nm. Said composite beam may further included a beam emitted at approximately 808 nm and a beam emitted at approximately 1064 nm.

[0028] The device may also include associated meters

or gauges showing information on the status of the device including its power level, the levels of its emitted light or similar information on the functioning of the specific device. The device may further be sold as part of a kit wherein the kit includes treatment protocols, maintenance protocols or other written materials that may focusing on the use of the device.

[0029] A composite beam of laser energy emitting energy at the frequencies claimed herein may also be prepared by modifying a commercially available laser such as a GaAlAs 808 nm Diode Pumped Solid State (DPSS) laser powered by a 500 mW driver. The device is fitted with suitable crystals to generate laser light of the appropriate, 532 nm, 808 nm and 1064 nm frequencies however commercially available laser devices do not emit such beams. The crystals may include a KTP (Potassium Titanium Oxide) crystal and an ND: YV04 (Yttrium Vanadate) crystals. DPSS lasers are equipped to filter energy from the 808 nm and 1064 nanometer frequencies and thus do not emit a composite beam. The device is modified by removing those filters and thereby emits electromagnetic radiation at those wavelengths in addition to the green laser light at 532 nm, something the device was incapable of doing as originally configured. The output of the laser shown in this embodiment consists of EMR as follows: up to 65 mW of 532 nm green laser light and as much as 435 mW of 808 nm and 1064 nm EMR. Further, the laser beam in this particular embodiment is emitted as a continuous wave rather than a pulsed beam. In other embodiments, however, pulsed beams may be generated and used.

[0030] Additionally, the focusing lens of the device is removed in order to generate a more diffuse beam which minimizes any thermal effect caused by the higher wavelength beams and the energy output of the device. The device shown is equipped with a shut-off switch which allows the health care provider to control the duration of the beam emission and ameliorate the risks of overheating the device. The device may be hand held when housed in a casing of suitable shape and size.

[0031] FIG. 2 shows a device according to the instant invention being applied to a condition under treatment, here a knee, 20. The beam, 21, which is comprised of energy at wavelengths of 532 nm, 808 nm and 1064 nm, is applied directly over the afflicted tissue at an angle of approximately 90°. Application at this angle will maximize penetration by the photonic energy of the dermal layers to varying depths according to the wavelength of the emitted energy. In treating musculo-skeletal pain, the tip of the laser device, 22, may be held directly against the treatment point for the afflicted area and applied in a linear, back and forth motion at a rate of approximately 1 inch every 3 seconds not to exceed a treatment duration of 30 seconds. The device is then turned off for at least approximately 5 seconds and the process is repeated for up to 10 times, depending on the extent and degree of injury and responsive feedback from the patient. Thus the dosage per treatment will usually range up to 150

Joules. Dosages vary per condition and severity, however, as prescribed by the health care provider. Further, actual dosage on the target tissue is variable with not all of the laser energy reaching the target tissue. Thus in many applications, the dosage at the surface of the skin significantly exceeds that on the target tissue.

[0032] As the therapy is administered, the laser deposits its energy in the form of photons within the afflicted cells. While not wishing to attribute the beneficial results achieved by the invention to any specific theory or modality, it appears that the application of EMR in accordance with the invention stimulates the nerves and increases circulation to the area under treatment. In turn, this increases blood flow and oxygen to the area under treatment and thus additional endorphins are released and pain enzymes are blocked.

[0033] Depending on the condition being treated, various effects appear to contribute to the efficacy of the treatment. For treating musculo-skeletal conditions such as sprains or strains, and other inflammations, the therapy may be applied as described above. By compressing the tissue as pressure is applied to the epidermis of the patient, the underlying, afflicted tissue structures may be brought into a closer proximity to the energy beam. Thus the different frequencies may reach the target tissues and energize the associated cells.

[0034] In treating musculo-skeletal pain, the treatment protocol concludes with the application of therapeutic light along the peripheral nerves and into the spinal segment where those nerves terminate and connect to the Central Nervous System. Laser Light Therapy is believed to enhance receptor activity on cell membranes associated with the production of endorphins. Accordingly, bio-stimulation by laser light enhances the production of endorphins with a resulting decrease in pain associated with the underlying condition. In addition, laser light is known to decrease production of bradykinin, which is one of the main causes of pain. Further, laser light therapy suppresses the excitation of the unmyelinated C-fibers, thereby alleviating pain associated with musculo-skeletal injury.

[0035] In treating wounds, the above treatment may be somewhat modified since direct contact with the wound may cause pain or discomfort or otherwise negatively effect the healing of the wound. In treating wounds, the laser is held immediately above the afflicted region and healthy tissue around the periphery. Application of the Laser Light Therapy has a positive effect on the production of granulation tissue during the proliferative phase of repairs. It also stimulates increased collagen synthesis as well as the activation and migration of macrophages and fibroblasts to the area of injury. Further Laser Light Therapy encourages the proliferation of mast cells as well as increases in endothelial cells and keratinocytes. In addition, Laser Light Therapy may increase the transport of ions, including possibly calcium ions, across the cell membrane and increase the cell's ability to transmit signals bringing about cell repair. Further-

more, the above effects all enhance the body's regenerative system to bring about wound healing.

[0036] Several more specific treatment protocols are variations on the above generalized therapy regimen. For treatment of persistent headaches, for example, the health care provider treats peripheral triggerpoints, including mid trapezius and suboccipital muscles with the application of laser light therapy and then treats the area of perceived head pain both with the laser barrel head contacting the skin.

[0037] The device may also be used to treat traumatized gum tissue, e.g. from a tooth extraction. In those cases, the health care provider should splay the beam over the area of involvement for at least 90 seconds. There should be no skin contact with the end of the barrel. Skin contact can then be made to trace the branches of the trigeminal nerve.

[0038] For oral mucosal trauma, the same protocol is an effective treatment.

[0039] Where treating joint pain in a patient, the health care provider applies EMR through directly contacting the laser head to the surface of the area to be treated irradiating the joint space, tendon attachments and the attendant muscle belly(s) with EMR. There should be a further continuation of nerve tracing to the spinal segment supplying the joint structures.

[0040] In treating acute cervical spinal injury with spasm and stiffness, for example, caused by auto accident, lifting injuries, or similar, the specific protocol is as follows. With the patient in a sitting position and the health care provider standing behind patient, the laser head of the device is applied with pressure to the skin over the spinous processes, interspinous ligaments, posterior cervical muscles, sternocleidomastoid muscle and mid trapezius (bilaterally). The treatment commences with a slow sweeping motion over the above-described areas. During treatment, the patient may complain of stinging pain over area of greatest inflammation. This will occur even with no skin contact. The patient is instructed to turn head to tolerance in order to stretch the involved tissues as laser light treatment is applied.

[0041] For a lumbar injury, the patient stands while supporting weight with hands on a table or wall in front of the patient. The health care provider applies the laser head to the patient's skin and moves the beam over the lumbar muscles, and medially to the interspinous ligaments, and medially to the spinous processes, all performed in a caudal to cephalic and then reversed motion. The beam is also run along the posterior thighs and calves. During treatment, the patient is instructed to bend forward to tolerance in order to stretch involved tissues. If possible, in the treatment of all spinal conditions, treatment should be performed while the spine is loaded and not while the patient is recumbent.

[0042] In the case of patients suffering from radiculopathies caused by spinal nerve root dysfunction, precipitated by biomechanical pressure or altered local physiology, the treatment may consist of irradiating the

entire neural pathway of the afflicted nerve, starting at the peripheral innervation and ending at the spinal segment that the nerve root exits from.

[0043] Furthermore, the treatment protocols may include variable dosages depending on the condition treated. Thus treatment dosages at the target tissue may include the following:

TREATMENT FOR RECENT INJURIES

Shoulder: 40-50 joules

Knee: 20 joules

Ankle: 40 joules

CONDITIONS

Strains: 5-10 joules per point. 35-50 joules total treatment

Osteoarthritis

- Interarticular: 4-8 joules per joint

- Extra articular: 2-4 joules per point

TOTAL DOSAGE

Ankle/Foot: 20-30 joules

Knee: 20-40 joules

Spine: 4-16 joules per vertebral motor unit, with additional treatment directed to the supporting musculature

These ranges are rough guides for treating some target tissue in response to some conditions and injury, but they are not intended as limitations. Indeed, higher dosages have been observed to yield positive and, at times, improved results.

[0044] The embodiment of the device disclosed in FIG. 1 has been tested on various patients suffering from a variety of musculo-skeletal conditions. For example, a 45-year-old female with a severe sprain on the left lateral ankle was treated pursuant to the therapy protocol outlined above and with the device described in FIG. 1. Unable to walk due to pain and severe swelling, laser light therapy was applied to the afflicted ankle over a total treatment period of five minutes. The result was a 75% reduction in swelling and an immediate ability to walk on the affected ankle with minimal pain. The effects of the treatment were not diminished by time and the patient had a full recovery in less time than would be expected due to the nature of this injury.

[0045] A 30-year-old female suffering from a complete tear of the anterior cruciate ligament was also treated. The patient had difficulty walking due to the injury. After applying the treatment outlined above with the same device, the patient reported markedly less pain on ambulation, even though the device did not repair the severed ligament.

[0046] Further, a 60-year-old male with a severe intercostal muscle sprain was treated 2 weeks post injury duration. The patient, employed as an industrial airconditioning mechanic was unable to perform job duties due to inability to fully extend left arm and twist trunk due to

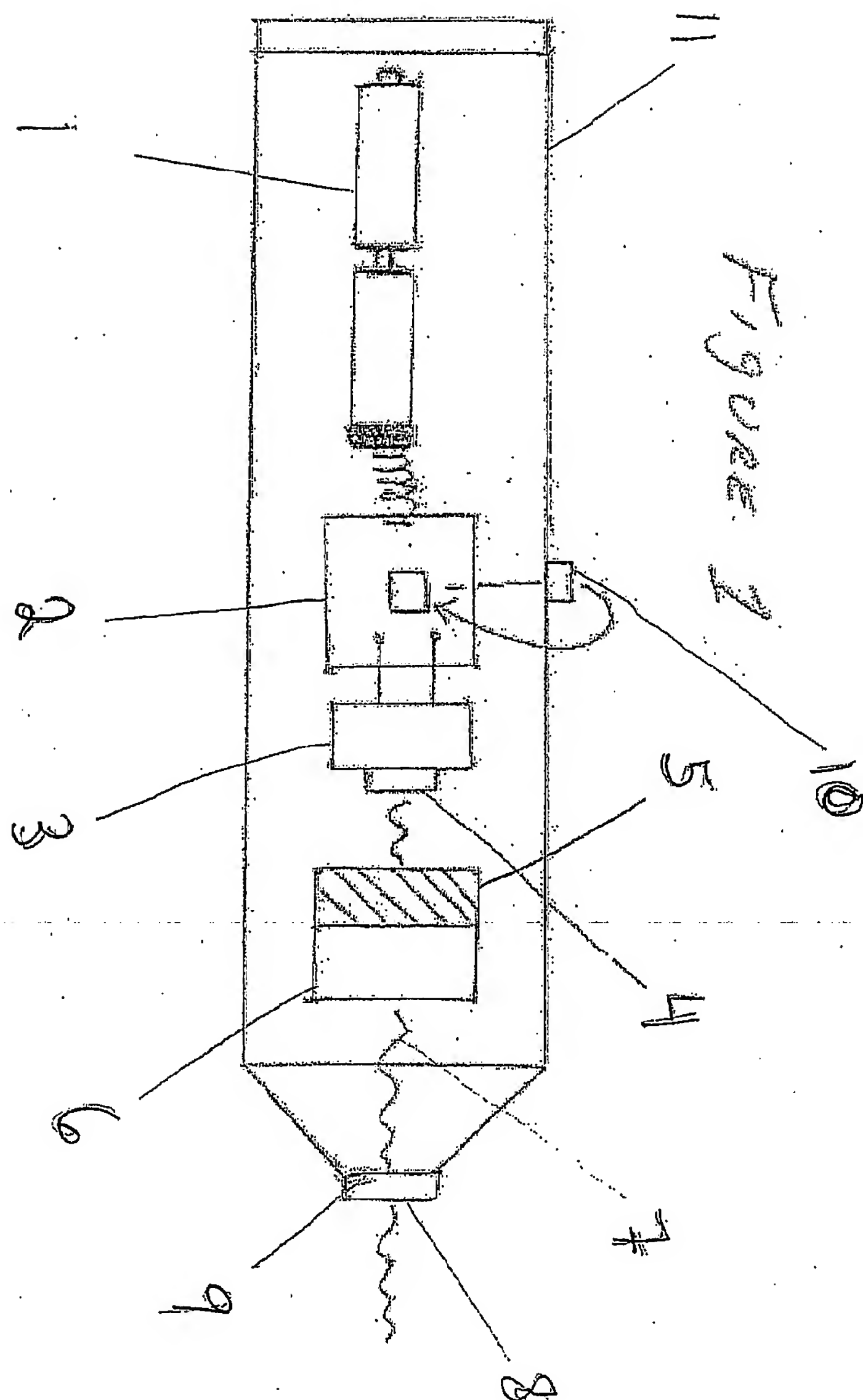
severe pain in the lateral rib cage. The patient was treated as set forth above with the same device over the affected area. Upon treatment, the patient was virtually asymptomatic and exhibited a full range of motion of the trunk and left arm. Follow-up research three days later re-

[0047] Further, a nonagenarian patient who had suffered a fall injuring her lower back, left knee and left foot. In addition, she suffered in part from a persistent numbness on the sole and lateral aspect of her left foot. The neuropathy was treated by application of laser light from the device along the injured foot, knee, the sciatic nerve distribution network and at the lumbar spine. As a result of the therapy, the patient reported that normal sensation in the previously numb foot had been restored.

[0048] Another patient suffering a bilateral rotator cuff tear was also treated with the device as outlined above. Prior to treatment, the patient exhibited an extremely limited range of motion with the injured shoulder. Post treatment, the patient was able to fully extend the injured shoulder. Although the pain associated with the torn rotator cuff did return, the palliative effect was pronounced and treatment was considered successful.

Claims

1. A laser therapy device for generating a composite laser beam comprised of a plurality of laser beams at least one of the plurality of beams being emitted at a wavelength of approximately 532 nm, a second such beam being emitted at a wavelength of approximately 808 nm and third such beam being emitted at a wavelength of approximately 1064 nm.
2. A laser therapy device comprising a power source, a driver board, an 808 nm pump laser diode, a microlens, a NDYV04 lasing crystal, a KTP lasing crystal, a collimating lens, and a single aperture, said device when in operation emitting a composite laser beam comprised of at least a first beam emitted at a frequency of approximately 532 nm, a second beam emitted at a frequency of approximately 808 nm and a third beam emitted at a frequency of approximately 1064 nm, said composite beam being emitted through a single aperture.
3. The laser therapy device in claim 2 wherein said device is housed in a hand held wand.
4. The laser therapy device of Claim 1 in which said device has a total power output of no more than 500 mW.
5. The laser therapy device of Claim 2 in which said device has a total power output of no more than 500 mW.
6. The laser therapy device of Claim 1 in which said device has a total power output of no more than 2W.
7. The laser therapy device of Claim 2 in which said device has a total power output of no more than 2W.
8. A method of providing laser therapy to a patient comprising the steps of;
 - diagnosing the patient's area of musculo-skeletal pain;
 - applying a laser therapy device at or near the surface of the patient's skin proximate to said area of musculo-skeletal pain;
 - causing said device to emit a composite laser beam comprised of beams emitted at a plurality of frequencies including at least one beam emitted at a frequency of approximately 532 nm, a second of said beams emitted at a frequency of approximately 808 nm, and a third of said beams emitted at a frequency of approximately 1064 nm; and
 - manipulating said device in a pattern and for a duration over said area of musculo-skeletal pain.
9. A method for generating a composite laser beam for use in administering laser light therapy comprising the steps of:
 - removing the infrared filter and the focusing lens of a 500 mW GaAlAs laser fitted with an ND: YV04 crystal and a KTP crystal; connecting said laser to a power source; causing said laser to emit a composite laser beam; the composite laser beam comprising component laser beams emitted at a frequency of approximately 532 nm, approximately 808 nm, and approximately 1064 nm; and emitting said composite beam over a relatively broad area.
10. A kit for treating musculo-skeletal pain comprising:
 - a laser therapy device capable of emitting a composite laser beam;
 - said composite laser beam being comprised of a plurality of laser beams;
 - said plurality including a laser beam emitted at a frequency of approximately 532 nm;
 - a second laser beam emitted at a frequency of approximately 808nm;
 - a third laser beam emitted at a frequency of approximately 1064 nm;
 - wherein said kit further includes written materials which may address information relating to the maintenance and use of said laser therapy device, various technical features of said device or treatment protocols, either general in nature or specific to various conditions.



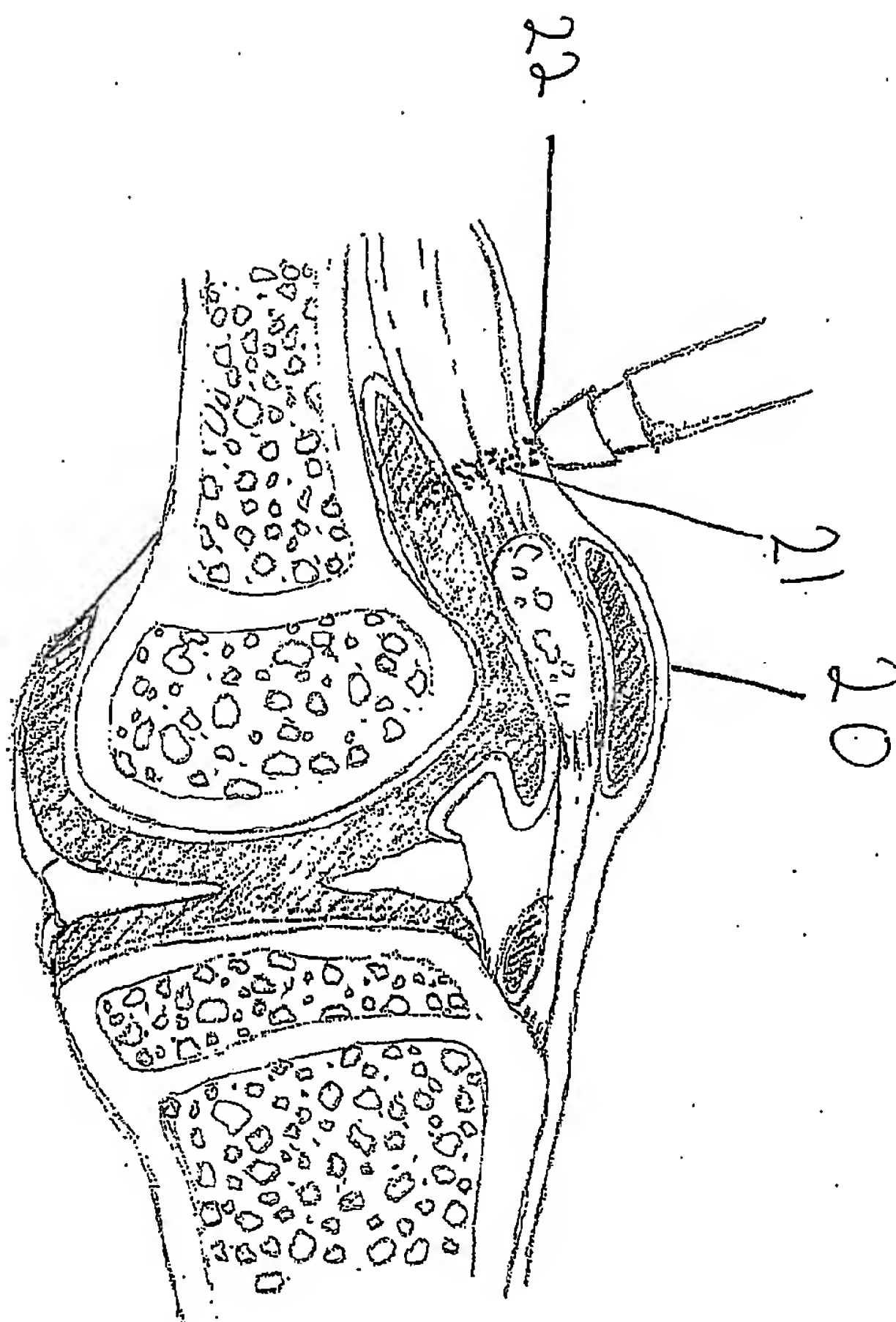


Fig. 2

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 (31) Convention Application No. 558 338
 (32) Filed 14 March 1975 in
 (33) United States of America (US)
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 (52) Index at acceptance A5R EC

(19)



(54) SURGICAL INSTRUMENT HAVING SELF-REGULATING
 RADIANT HEATING OF ITS CUTTING EDGE

(71) I, ROBERT F. SHAW, 135 Willowbrook Drive, Portola Valley, California 94025, a citizen of the United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The invention is concerned with a surgical cutting instrument having self-regulated radiant heating of its cutting edge and with a method of using it; the invention is related to those disclosed in the complete specifications of my co-pending U.K. patent applications Nos. 7694/76, 7695/76, 7697/76, 7698/76 and 7699/76 (Serial Nos. 1,546,623, 1,546,624, 1,546,626, 1,546,627, 1,546,628).

The control of bleeding during surgery accounts for a major portion of the total time involved in an operation. The bleeding that occurs from the plethora of small blood vessels that pervade all tissues whenever tissues are incised obscures the surgeon's vision, reduces his precision, and often dictates slow and elaborate procedures in surgical operations. It is well known to heat the tissues to minimize bleeding from incisions, and surgical scalpels which are designed to elevate tissue temperatures and minimize bleeding are also well known. One such scalpel transmits high frequency, high energy sparks from a small electrode held in the surgeon's hand to the tissues, where they are converted to heat. Typically, substantial electrical currents pass through the patient's body to a large electrode beneath the patient, which completes the electrical circuit. Discharge of sparks and temperature conversion in the tissue are poorly controlled in distribution and intensity, and erratic muscular contractions in the patient are produced so that this apparatus cannot be used to perform precise surgery. Further, apparatus of this type frequently produce severe tissue damage and debris in the form of charred and dead tissue, which materially interfere with wound healing.

Another well-known surgical scalpel em-

plays a blade with a resistive heating element which cuts the tissue and provides simultaneous hemostasis. Although these resistive elements can be readily brought to a suitably high and constant temperature in air prior to contacting tissues, as soon as portions of the blade come in contact with tissues, they are rapidly cooled. During surgery, non-predictable and continuously varying portions of the blade contact the tissues as they are being cut. As the blade cools, the tissue cutting and hemostasis become markedly less effective and tissue tends to adhere to the blade. If additional power is applied by conventional means to counteract this cooling, this additional power is dissipated to the uncooled portions of the blade, frequently resulting in excessive temperatures which may result in tissue damage and blade destruction. This results from the fact that in certain known resistively heated scalpels, the heating is a function of the current squared times the resistance (I^2R). In conventional metallic blades of this type, the higher the temperature of any blade portion, the greater its electrical resistance, and consequently the greater the heating resulting from the power input.

It is generally recognized that to seal tissues and effect hemostasis it is desirable to operate at a temperature between 300° C. and 1000° C. And for reasons noted above, it is desirable that electrothermal hemostatic surgical cutting instruments include a mechanism by which power is selectively delivered to those portions of the cutting edge that are cooled by tissue contact so that the blade may be maintained at a substantially uniform operating temperature within the desired optimal range. Recently, hemostatic scalpels have been described (see, for example, U.S. Patent Specifications Nos. 3,768,482 and 3,826,263) in which the temperature-controlling mechanisms include resistive heating elements disposed on the surface of the scalpel blade. However, such instruments require precision in fabricating the dimensions of the heating elements to obtain the desired

resistances. And such resistive heating elements may be subjected to variations in resistance during use, as tissue juices and proteins become deposited upon the surface of the blade.

The present invention provides a cutting instrument comprising a blade having a cutting edge and an aperture remote from the cutting edge for introducing electromagnetic radiation into the blade, the blade being substantially transparent to the electromagnetic radiation between the aperture and the cutting edge, and electromagnetic radiation absorbing means disposed solely adjacent said cutting edge for heating the cutting edge.

The preferred embodiment of the present invention provides a surgical cutting instrument in which the cutting portion of the blade is brought to an elevated temperature by heating of the blade by thermal radiation. Radiant energy from a source such as a high temperature filament or ribbon or a laser is optically coupled to a substantially transparent blade an edge on which has been sharpened to form the cutting edge of the instrument. A non-radiation-transmitting internally-reflecting surface prevents loss of radiant energy from within the blade. The resultant scattering of light by internal reflections tends to distribute radiant energy throughout the interior of blade, and the optical scattering may be further enhanced by the incorporation of particulate scattering elements within the blade material.

Beneath the internally-reflecting coating and only adjacent the cutting edge of the blade, there is disposed a radiation-absorbing material which absorbs and converts the radiant energy to heat which is conducted through the material to the cutting edge to bring it to operating temperatures. The average temperature along the cutting edge may be adjusted by adjusting the power supplied by the radiation source, for example, by adjusting the electrical signals applied thereto.

Heating of those portions of the cutting edge that are cooled by tissue contact in order to maintain cutting temperatures sufficiently constant (i.e., temperature self-regulation) may be accomplished by fabricating the radiation absorber adjacent the cutting edge from a material which substantially increases in radiation absorption coefficient with decreasing temperature within the operating temperature range. Since each local region of the material absorbs the distributed radiation in accordance with its local absorption coefficient, each local region may have its temperature regulated independently of the operating temperature of adjacent regions. Thus, even in the presence of unpredictable and substantial variations in the cooling of the various regions of the heated edge resulting from the edge being manipulated to cut tissues, all regions along the length of the

cutting edge can be maintained within a suitably constant temperature range. Known thermochromic materials which have absorption coefficients that vary as a function of temperature may be used as the radiation-absorbing material in the surgical instrument of the present invention.

In the accompanying drawings:—

Figure 1 is a partial side view of a surgical cutting instrument according to one embodiment of the present invention;

Figure 2 is an end view along the line 2—2 of the instrument of Figure 1 showing the blade and the radiation source therein;

Figure 3 is a partial side view of an alternative embodiment of the present invention;

Figure 4 is an end view along the line 4—4 of the instrument of Figure 3 showing the optical channels therein for distributing radiation from a remote source; and

Figure 5 is a partial side view of another embodiment which employs segmented thermochromic regions.

Referring now to Figure 1, there is shown a partial side view of a surgical cutting instrument which has a blade 9 that is suitably attached to handle 11. A high-intensity light or thermal radiation source within the handle 11 includes a lineally-mounted incandescent filament 13 that is disposed within a parabolic reflector 15 which is oriented to direct the radiant energy from the filament toward the cutting edge 17 and facets 16 at a lower portion 18 of the blade. The lineally-mounted filament 13 assures adequate distribution of the radiant energy therefrom substantially over the length of the cutting edge 17 of blade 9. The electrical power to heat the filament 13 is applied thereto by A.C. or D.C. source 20 via conductors 21 and 22. A photodetector 30 is optically coupled to the interior of the blade 9 and is electrically connected to the power source 20 through a conventional servo-regulator 31 in a manner which controls the average power applied to the filament 13 in response to amount of radiant flux detected by photodetector 30.

Referring now to Figure 2, there is shown a cross section of the apparatus of Figure 1 including the filament 13 and the reflector 15 that directs radiant flux 5 substantially toward the facets 16 and cutting edge 17 of the blade 9. The filament 13, parabolic reflector 15 and radiation-transmitting window 14 may be formed into a chamber which is evacuated or filled with inert gas to minimize oxidation of the incandescent filament 13. The interior material of blade 9 should transmit and scatter well the radiant energy at the wavelengths of the flux 5 from filament 13 but should absorb poorly or not at all at these wavelengths. A reflective optical coating 8 is disposed over the parabolic reflector and over the internal surfaces of the blade

side walls 6 and 7 and the facets 16 of blade 9, but not over the window 14 through which the flux from the filament 13 is coupled to the blade 9. A layer 10 of radiation-absorbing, thermochromic material is disposed at the facets 16 of blade 9 adjacent the reflective coating 8 and acts as a collector of the radiant flux 5 from filament 13. The radiant flux 5 collected in layer 10 is converted to heat which is conducted to the cutting edge 17.

Thermochromic materials which have radiation absorption coefficients that vary as a function of temperature may be used as the radiation-absorbing material of layer 10. Materials which exhibit thermochromic properties in selected temperature ranges include indium antimonide, gallium antimonide, and other semiconductors, zinc oxide, some lead salts, some organic and other inorganic materials.

Only a portion of the radiation which illuminates the absorbing material of layer 10 is absorbed. The remaining non-absorbed portion of the radiation is transmitted through the layer 10 and is internally reflected by the reflective coating 8 back through the layer 10 (where further absorption occurs) and re-emerges in the substantially transparent interior region of the blade 9 which is remote from the cutting edge where it follows a multi-reflective path. As the temperature of the absorbing material 10 and hence of the cutting edge 17 increases, absorption by the material of layer 10 decreases and the average radiant flux in the transparent region of the blade 9 increases. Conversely, as the heated regions of the cutting edge 17 cool upon contact with tissue being cut, radiation absorption by the material of layer 10 increases and the average radiant flux in the transparent region 9 of the blade 9 decreases. The photodetector 30 may be coupled to the interior of the blade for monitoring the average radiant flux within the blade to increase or decrease the power supplied by the source 20 to the filament 13 as required.

Absorption by layer 10 of the wavelengths of radiant energy produced by filament 13 thus experiences increments for temperature decrements within the operating range of the cutting edge, from 300° C. to 1000° C. It is this radiation absorption property of the material of layer 10 that provides the self-regulating means by which local regions of the cutting edge 17 that cool upon contact with tissue being cut are radiantly heated at an increased rate by increased absorption of radiation. Other local regions of the cutting edge not cooled upon contact with tissue being cut do not exhibit increased absorption and therefore do not substantially change in their conversion of radiant energy into heat. Thus, as the temperature varies in various regions of facets 16 and the layer 10 disposed

thereon, the radiation absorption of these regions vary inversely to assure increased radiation absorption of the cooled regions sufficient to maintain the operating temperature thereof within the desired operating range.

As the layer 10 and cutting edge 17 heat up prior to cutting, the layer 10 becomes less absorptive and greater amounts of radiant flux 5 are reflected from layer 10 or are transmitted through layer 10 to be internally reflected by the reflective coating 8. This increases the radiation flux within the material such as glass or quartz, of blade 9. Radiation scattering centers such as rutile fibers, quartz particles, may be dispersed through the transparent region of the blade 9. The increased radiation flux in the transparent region of the blade 9 is detected by photodetector 30 which is connected through a conventional servo-regulator 31 to the power source 20 to decrease the power supplied to filament 13. The temperature of layer 10 and cutting edge 17 and facets 16 is thus stabilized within a preselected operating range. Conversely, as portions of the cutting edge 17 and facets 16 are cooled upon contact with tissue being cut, the material of layer 10 in the locally-cooled regions increases the absorption of radiant flux and decreases the level of flux in the portion of blade 9 sensed by detector 30, and this acts through servo-regulator 31 to increase the power supplied by power source 20 to the filament 13. Where it is desirable to maintain a relatively uniform wavelength spectrum of radiant energy over the range of power dissipation of the cutting instrument, the amount of surface area of the filament 13 heated to a specified temperature may be varied, by retracting into the handle, or rotating within an aperture to vary the amount of radiant flux, rather than varying the temperature of the filament operating with a fixed, exposed area.

Alternatively, a relatively fixed spectrum can be accomplished by utilizing a filter between window 14 and the blade. Such a filter may also be used to narrow the bandwidth of the radiant energy, and thereby simplify the selection of absorbing materials used in layer 10 or, the filament 13 may be replaced by the ionized gas column of a gas discharge tube which emits radiant energy within one or a few characteristically narrow spectral lines, and which thus also simplifies the selection of absorbing materials used in layer 10.

Referring now to Figures 3 and 4, there are shown side and end views, respectively, of an alternative embodiment of the present invention in which the radiant source is disposed remotely from the cutting instrument. Fiber optic filaments are aligned in a linear array 33 to irradiate the absorbing layer 10. A photodetector 30 may be disposed within

the handle 11 to detect the level of radiant flux and to produce a control signal on line 35 in response thereto for controlling the power output from the remote source 37, such as a laser. Alternatively, selected fibers in the array 33 can be used to sample radiant flux at locations along the length of the blade and illuminate a photodetector, thereby to produce the requisite power-controlling signal. Also, other optical means such as reflective mirrors and lenses may be used instead of the optical fibers to direct the radiant energy from the remote source into the absorbing layer 10.

Figure 5 illustrates still another embodiment of the present invention in which the material of the absorbing layers 10a, 10b, 10c, etc. exhibits relatively constant absorption characteristic for converting radiant energy into heat for heating cutting edge 17 and also serves as an infrared radiation source whose radiation spectrum is a measure of its temperature. The illuminating 41a, 43a, etc. and detecting 41b, 43b, etc. fibers going to and coming from short discrete segments of the absorbing layer 10a, 10b, 10c, etc. can be gathered into two separate bundles for each segment. By utilizing a separate radiant source 47, 49, 51, etc. to illuminate the radiation absorbing material of each segment 10a, 10b, 10c, etc. and a separate detector for each source associated with each detecting fiber 41b, 43b, etc., the temperature of each segment can be independently monitored and the power output of the corresponding radiant source can be independently regulated so that the temperature of each segment along the cutting edge 17 can be maintained within a suitably constant temperature range, independent of the other segments along the cutting edge. Utilizing this principle, a rapidly-responding radiant source and detector may be time-shared among several segments along the length of the cutting edge 17. Further, a plurality of individual filaments of the type previously described with reference to Figures 1 and 2 may be lineally positioned along the length of the cutting edge 17 in order to independently elevate and regulate the temperature of a corresponding segment, independently of the temperature of an adjacent segment.

WHAT I CLAIM IS:—

1. A cutting instrument comprising a blade having a cutting edge and an aperture remote from the cutting edge for introducing electromagnetic radiation into the blade, the blade being substantially transparent to the electromagnetic radiation between the aperture and

the cutting edge and electromagnetic radiation absorbing means disposed solely adjacent said cutting edge for heating the cutting edge.

2. A cutting instrument according to claim 1, wherein radiation reflecting means is disposed on surfaces of the blade to contain radiant energy therein.

3. A cutting instrument according to claim 1, wherein the radiation absorbing means exhibits increased absorption in response to decrease in temperature over a portion of the temperature range from 300° C. to 1000° C.

4. A cutting instrument according to claim 1, wherein the radiation absorbing means exhibits increased reflectance of radiation for increased temperature over a portion of the temperature range from 300° C. to 1000° C.

5. A cutting instrument according to claim 1, wherein the radiation absorbing means exhibits increased transmission of radiation for increased temperature over a portion of the temperature range from 300° C. to 1000° C.

6. A cutting instrument according to claim 1, wherein radiation scattering means is provided within the transparent portion of the blade.

7. A cutting instrument according to any one of the preceding claims, wherein a source of electromagnetic radiation is coupled through the aperture to irradiate the radiation absorbing means.

8. A cutting instrument according to claim 7, wherein the source of radiation includes an incandescent filament.

9. A cutting instrument according to claim 7, wherein the source includes a gas-discharge source.

10. A cutting instrument according to claim 9, wherein the gas-discharge source includes a laser.

11. A cutting instrument according to claim 7, wherein the source of radiation is connected to the aperture by reflecting means.

12. A cutting instrument according to claim 7, wherein the source of radiation is connected to the aperture by optical fibers.

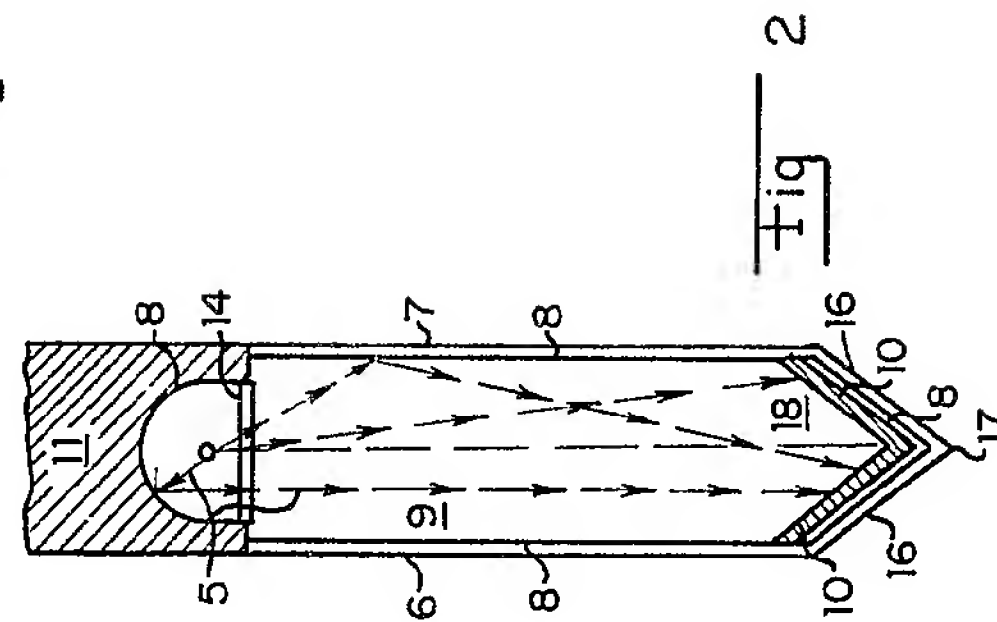
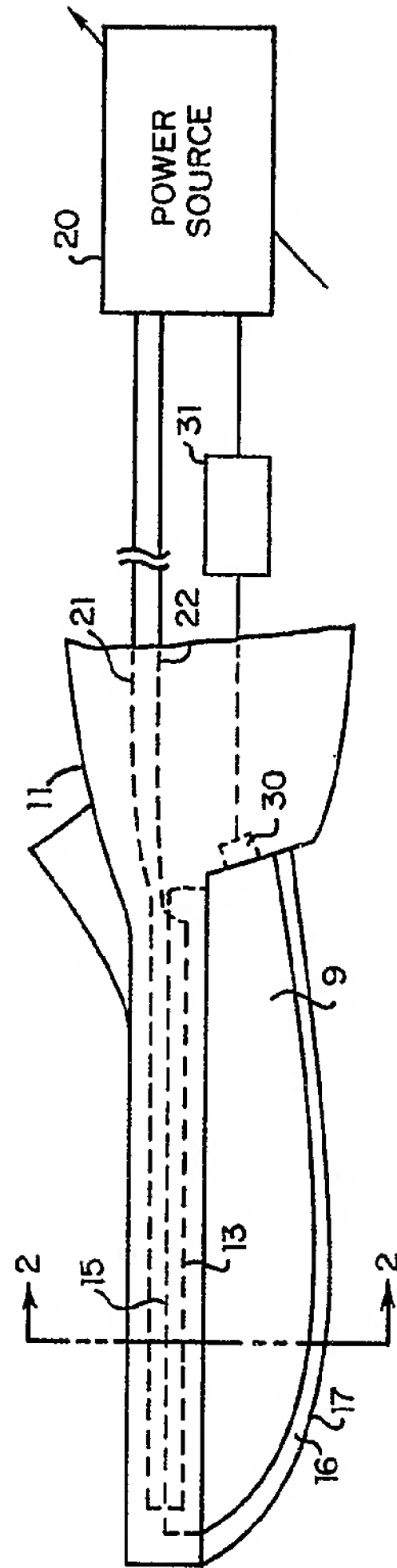
13. A cutting instrument according to any of the preceding claims, wherein photoresponsive means is disposed to produce a control signal in response to the amount of radiation within the blade.

14. A cutting instrument according to claim 13, wherein the source of radiation can receive the control signal for altering the level of radiation produced by the source to maintain the average temperature of the radiation absorbing means within a selected operating temperature range.

15. A cutting instrument substantially as hereinbefore described with reference to the accompanying drawings.

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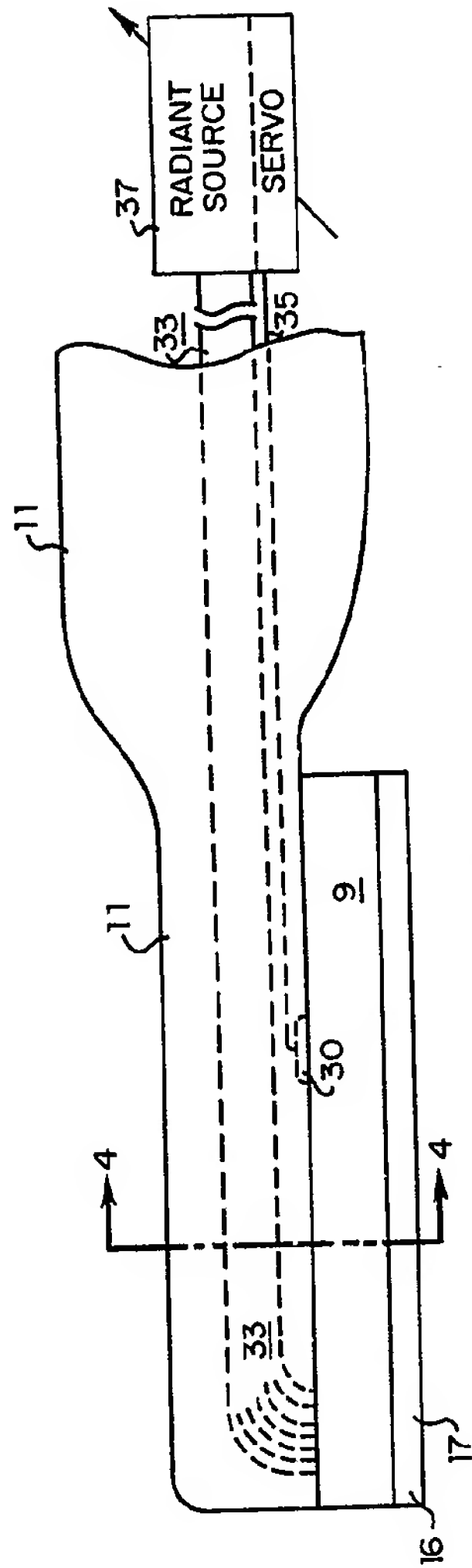


Fig 3

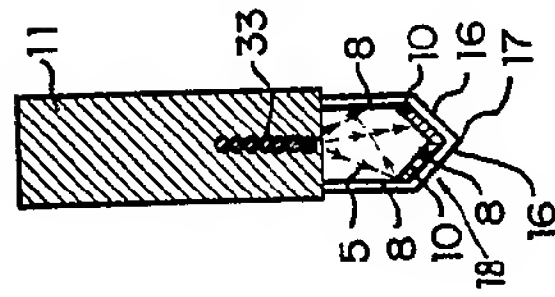


Fig 4

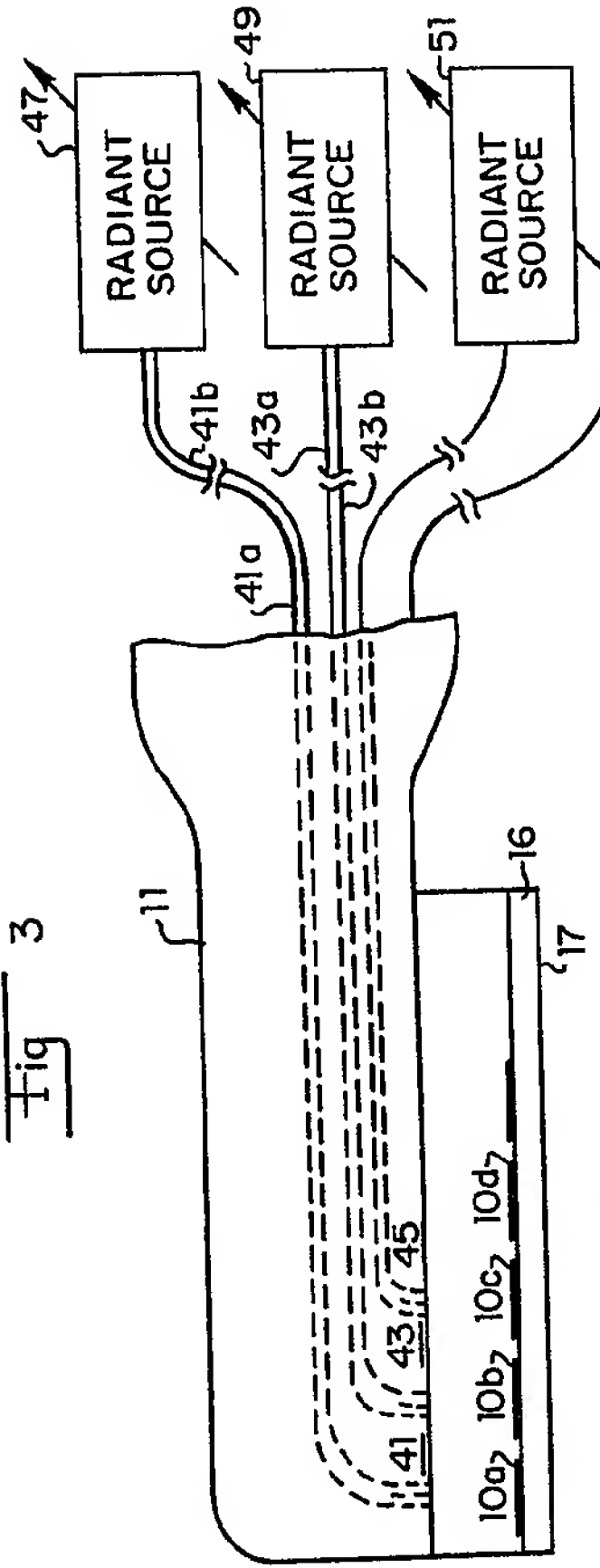


Fig 5

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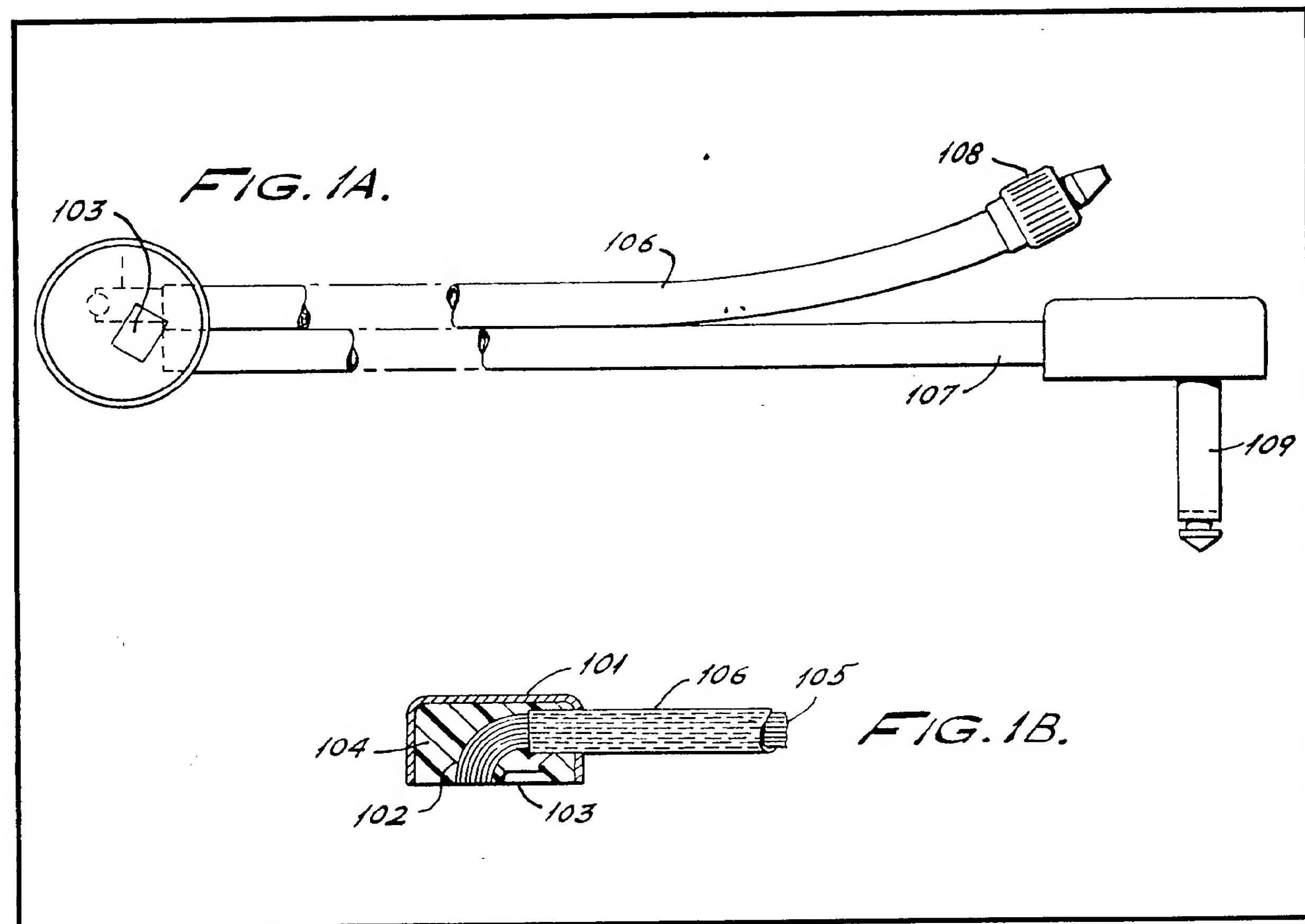
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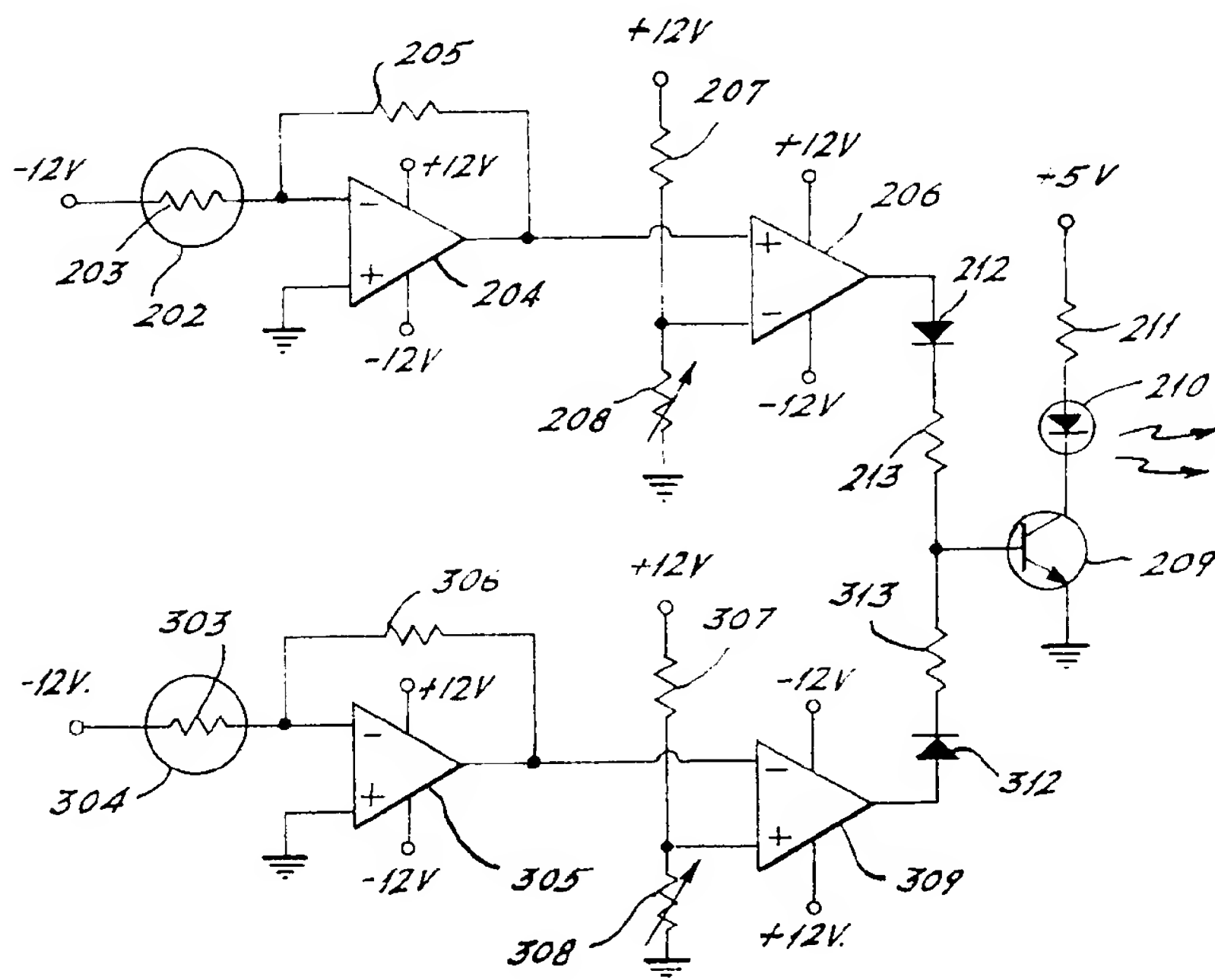
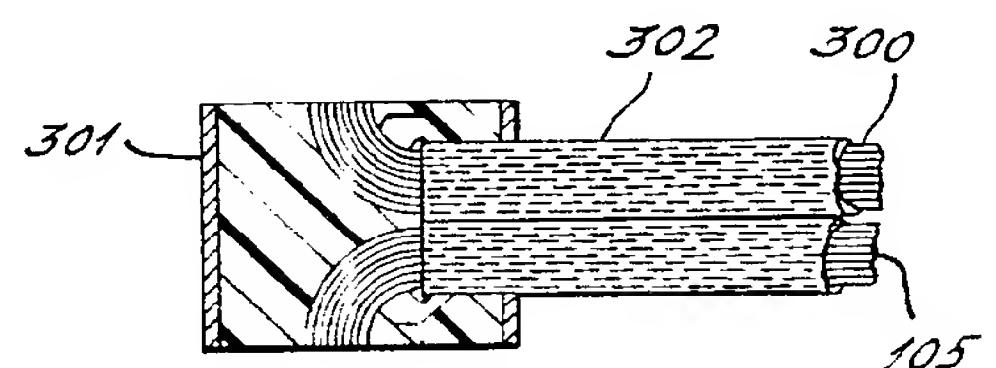
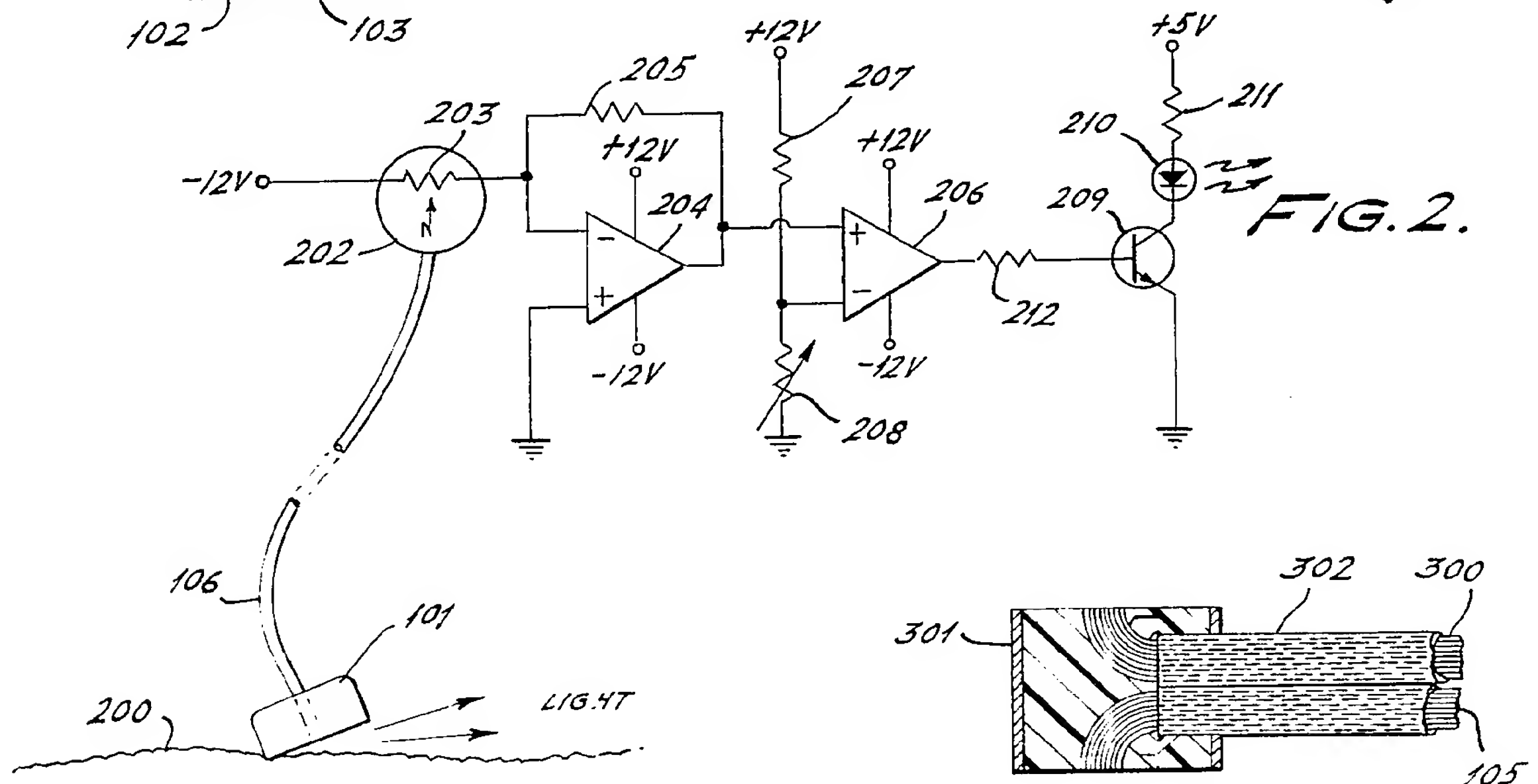
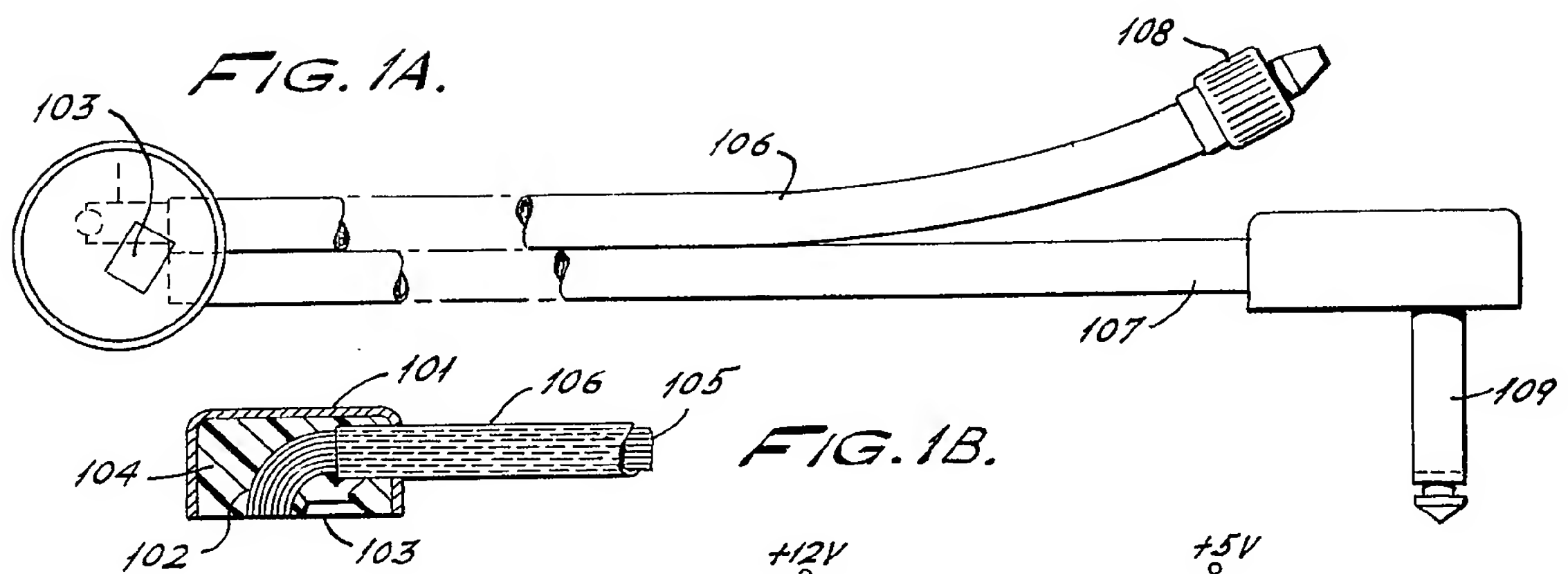
Coventry CV1 1NP

(54) Photo-electric detection of probe dislodgement

(57) When a probe having a contact surface adapted to be placed on a surface of the body to monitor or control a body function is dislodged from the body, an increased radiation level impinges on the contact surface and radiation receiving means 105 located in the contact surface sense the increased radiation level and provide an indication

of probe dislodgement. A skin temperature probe having a thermistor 103 at the skin contact face has a bundle of optical fibres 105 ending at that face for detection of light when the probe is dislodged, and may have a second bundle of fibres ending at the opposite face for detection of covering of the probe e.g. by a blanket.





SPECIFICATION

Apparatus for detecting probe dislodgement

5 The invention relates to skin contact probes, and more particularly to apparatus for detecting dislodgement of such probes. Although the invention will be described in connection with a probe having means for sensing body
10 temperature, it will be apparent that the invention has broader application. The invention may be extended to probes which monitor other body functions and to probes which control or influence a body state or condition.
15 As an example, several devices, in common use, provide thermal environmental control by positioning temperature probes which are intended to be maintained in intimate contact with the skin and by utilizing such probes to
20 control operation of a heater for incubators and radiant warmers. Typically, such probes involve a thermoelectric transducer mounted on a skin contact surface. Electrical signals from the transducer are utilized for heater
25 control. In such instances, it is essential to maintain intimate contact between the probe and the skin, and particularly to maintain contact with the skin and the rather sensitive thermoelectric transducer. Should the probe
30 become completely dislodged, there is the possibility of having it contact a hot or cold surface, with consequent derangement of the thermal environment. Even a small discontinuity between probe and skin, short of total
35 dislodgement, can work adversely to proper control of the thermal environment. Furthermore, it is important to know when a system, provided for identifying probe dislodgement, is rendered ineffective to perform this func-
40 tion.

It is an object of the present invention to provide apparatus for detecting dislodgement of skin contact probes, and more particularly to detect even rather slight discontinuities
45 between the probe and the skin.

It is a more particular object of the present invention to provide apparatus which senses probe dislodgement based on the receipt of ambient light, or radiation from specific
50 sources, at the skin contact surface of the probe when mounted on the skin.

It is a still further object that the apparatus for sensing probe dislodgement by light reception being capable of discriminating between
55 light associated with the dislodgement, and light which arrives through skin translucence during adequate contact, and furthermore that it does so independently of the pigmentation of the skin of the subject.

60 Yet another object of the present invention is to provide a probe which develops an indication when the probe is covered and thereby prevented from sensing dislodgement.

The present invention senses increased radi-
65 ation levels attendant to dislodgement of a

contact probe from a skin surface with which it is placed in contact. Transducer means having a light receiving portion located in the skin contact surface of the probe sense the
70 increased radiation level impinging on the probe contact surface when the probe is dislodged and a radiation signal is developed representative of the radiation level impinging upon the contact surface. When a threshold is
75 exceeded, indicating dislodgement, an alarm circuit is energized. The alarm threshold may be adjusted to meet carying conditions of ambient light, skin pigmentation and the like.

According to the invention, apparatus for
80 sensing probe dislodgement comprises a probe housing having a contact surface adapted for contact with a body; transducer means having a radiation receiving portion located in said contact surface for sensing an
85 increased radiation level impinging upon said contact surface when said probe housing is dislodged from said body and said contact surface is exposed to said increased radiation level, and for developing a radiation signal
90 representative of the radiation level impinging upon said contact surface; means for supplying a threshold signal representative of a predetermined radiation level less than said
95 increased radiation level impinging upon said contact surface when said probe is dislodged from said body, and alarm means responsive to said radiation signal and said threshold signal for developing an indication when said
100 radiation level impinging upon said contact surface exceeds said predetermined radiation level.

The invention may also provide a probe for sensing a body function, the probe comprising a probe housing having a contact surface
105 arranged to contact a body; a sensor located in said contact surface and responsive to said body function; radiation receiving means located in said contact surface for sensing an increased radiation level impinging upon said
110 contact surface when said probe housing is dislodged from said body and said contact surface is exposed to said increased radiation level, and means emanating from said housing for transmitting the outputs of said sensor
115 and said radiation receiving means to a distant location.

The invention may particularly provide apparatus for sensing skin contact probe dislodgement, the apparatus comprising housing
120 means defining a skin contact surface for said probe; photo-receptive means located on said skin contact surface of said housing means; alarm means, energized by reception by said photo-receptive means of light, having an intensity exceeding a predetermined level, said
125 alarm means being placed remotely from said housing means, and photo-transmitting means extending out from said housing means for connecting said housing means, photo-recep-
130 tive means and said alarm means.

Two embodiments of a probe and associated circuitry in accordance with the invention are now described by way of example with reference to the accompanying drawings, in which:—

Figures 1a and 1b show, respectively, a bottom view and a side cutaway view of a probe embodying the principles of the present invention;

Figure 2 shows a schematic circuit for detecting and displaying probe dislodgement conditions;

Figure 3 is a side cutaway view of another embodiment of a probe embodying the principles of the present invention; and

Figure 4 shows a schematic circuit useful with the probe of *Fig. 3* for detecting and displaying probe dislodgement conditions.

Referring first to *Figs. 1a and 1b*, there is shown a skin temperature probe embodying the principles of the present invention. In the *Figures*, a thermistor 103 is employed, as is conventional in thermal sensing skin contact probes. Electrical signals from the thermistor 103, corresponding to skin temperature changes, are coupled via cable 107 and jack 109 to the heater controls, there to enable appropriate changes in the thermal environment to correspondingly increase or decrease the skin temperature of the subject. The probe is defined by an outer housing 101, which is shown to have a generally cylindrical configuration, but which, it will be appreciated, may vary in accordance with the characteristics of the subject and the needs of the designer. The lower, or skin contact surface of the probe, carries not only the thermistor 103, but also the end of a fibre-optic bundle 105, suitable optically prepared for receipt and conveyance of impinging light, be it ambient light or light from a specific source.

Fibre-optic bundle 105 passes through a rigid elbow 102 directing the bundle toward and through the outside of the housing 101. A potting compound 104, such as epoxy resin or the like, not only holds the fibre-optic bundle 105 and the thermistor 103 in place within the housing 101, but also defines generally the skin contact surface thereof and holds the position of the optically prepared end of fibre-optic bundle 105 and the thermistor 103 thereon. A hollow conduit 106 encloses the fibre-optic bundle 105 between the probe, monitor and alarm circuitry described below. A suitable connector 108 is provided at the free end of conduit 106.

In the embodiment shown, *Figs. 1a and 1b*, the fibre-optic bundle 105 is maintained clustered together, generally at the centre of the skin contact surface, and in relatively close proximity to the thermistor 103. The housing 101 and the conduit 106 are opaque, whereby ambient light will not impinge on the sides of the fibre-optic bundle 105, and the only light in bundle 105 will arrive from the

input end of the probe-skin contact surface. Likewise, loss of light in transmission along bundle 105 is thereby prevented.

In an alternative embodiment, respective portions of the optical fibres 105 may be arrayed at disparate points on the skin contact surface, for example at the periphery thereof or surrounding the thermistor 103. In such event, the elbow casing 102 may not be required, with the respective fibres converging into a bundle near the exit from the housing 101, thence traversing the interior of conduit 106.

Any of the embodiments of the present invention may employ an extensive variety of configurations for the probe 101, including for example, the entire probe structure, corresponding to housing 101 and potting compound 104 may be fabricated of an integral moulding, about the optical interface at the termination of bundle 105, and the thermistor 103. Many commercially available materials are suitable for such an application, polyurethane rubber moulding compound being one of them. Moreover, a separate light source may be provided in proximity to the probe 101 to provide a source of light for the functioning of the monitor and alarm of the invention especially when there is an absence of ambient light. Alternatively, the separate light source may be remote from the probe and the light conducted to the probe through a fibre-optic bundle.

As shown in *Fig. 2*, the probe 101 may be disposed against the skin 200 of a subject in a dislodgement position whereby ambient light impinges on the skin contact surface of the probe. The apparatus for holding the probe in place is not shown. This may involve tape, belts, straps, or the like. In such an event, light received at the optical interface as a result of dislodgement is conveyed via the fibre-optic bundle 105 within conduit 106 to an optical detector 203. The circle identified by reference number 202 represents a receptacle which receives and engages connector 108 of conduit 106.

Numerous types of optical detectors 203 are available, each with its own respective operational characteristics. The preferred embodiment herein utilizes a detector 203 having a preference for sensitivity, rather than operational speed. Generally, all types of commercially available photosensors function within a time responsiveness range satisfactory to render a timely alarm in response to the light impinging on the probe bundle 105 upon dislodgement. However, some photoelectric transducers possess sensitivity characteristics which are preferable to others for purposes of the present invention. In a preferred embodiment, the photosensor 203 is a photoconductive cell of the cadmium sulphide type, for example, those available under the commercial designation "Clairex CL 909L"

cell. It is to be understood, however, that depending on the system to which the invention is applied, and the particular sensitivity/responsiveness constraints thereon, the photo-

5 detector 203 may also be embodied as a photo-Darlington transistor, a PIN transistor, a PIN silicon photo diode, a photovoltaic cell, or the like.

The photodetector 203 is connected to a
10 - 12 volt supply. A current change produced by a change in the conductivity of the photodetector 203 when energized by light from the fibre-optic bundle is coupled to the inverting input of an amplifier 204, the non-inverting input of which is held at ground, that is
15 earthed. Amplifier 204 is arranged with resistor 205 in a feedback configuration to the inverting input. The amplifier 204 fulfills the function of a linear detection of current from
20 photosensor 203, and therefore preferably involves strong current sensing capabilities with negligible bias currents over the operating temperature involved. In a preferred embodiment, amplifier 204 is implemented by a high
25 input impedance operational amplifier such as those having junction field-effect transistor (JFET) input stages, for example those available under the commercial designation "National LF355" integrated circuits.

30 The output of amplifier 204 is coupled to the non-inverting input of a comparator-amplifier 206 which functions as a threshold circuit. The inverting input of amplifier 206 is coupled to the central point of a voltage
35 divider comprising resistors 207 and 208 connected between a + 12 voltage supply and ground. Hence, the signal at the non-inverting input of amplifier 206 will cause amplifier 206 to go positive depending upon
40 input signal amplitude relative to the threshold voltage from divider 207 and 208. The threshold voltage is set to represent a predetermined light level corresponding to the level of background light reaching the end of fibre-
45 optic bundle 105 when the skin contact surface of the probe is in contact with the skin. Amplifier 206 is the type commercially available under the trade designation "LM301".

Comparator-amplifier 206 has its output
50 coupled through a resistor 212 to the base of a transistor 209, which has a light emitting diode 210 in its collector circuit. The light emitting diode 210 is connected in series with a resistor 211 between a + 5 volt supply and
55 the collector of the transistor 209 while the emitter of this transistor 209 is tied to ground, i.e. it is earthed.

When the voltage from amplifier 204 to comparator 206 exceeds the threshold voltage
60 established by the divider 207 and 208 transistor 209 is turned on, and diode 210 is switched into the conducting state. The light emitted serves to alarm the condition of dislodgement, indicating to the operator of the
65 system that the probe 101 has become dis-

lodged from the skin 200.

Resistor 208 is shown as a variable resistor, thereby affording an adjustment facility to the threshold of comparator 206, in order to
70 account for anticipated ranges of ambient light, circuit sensitivity-parameters, and skin pigmentation and translucence characteristics. Depending upon the application desired, the resistor 208 may be preset during a calibration
75 process, or may be variable in accordance with the needs of the operator.

It is to be understood that audible alarm systems may be utilized in substitution for, or in conjunction with the light emitting diode
80 210.

The invention operates wherein, should the probe 101 become partially dislodged from the skin 200, ambient light will impinge on the skin contact surface of the probe, and will
85 be conveyed by the fibre-optic bundle 105 within conduit 106 to the photosensor 203. An electrical signal is produced thereby, processed at amplifier 204 and comparator 206, and the alarm diode 210 is energized upon
90 the activation of transistor 209.

Fig. 3 shows a second embodiment of a probe constructed in accordance with the present invention and provided with means for sensing when the probe is covered so as to be
95 shielded from sources of light and rendered ineffective. In use, a body probe may become covered by a blanket, bandage or piece of equipment. When this occurs, an optical sensing technique for detecting probe dislodgement will not function properly, if at all, if the
100 light sensor is shielded from the ambient light or a specific source of light. In the Fig. 3 probe, a second fibre-optic bundle 300 is provided which opens into the top surface of probe housing 301. A hollow conduit 302
105 encloses fibre-optic bundle 300 between the probe and the alarm circuitry shown in Fig. 4.

Under normal operating conditions, fibre-optic bundle 105 transmits no light or very
110 little light while the contact surface of housing 301 is in contact with the skin. At the same time fibre-optic bundle 300 transmits the light impinging upon the top surface of housing 301. If the probe becomes covered by a
115 blanket or the like, the light level transmitted by fibre-optic bundle 300 drops significantly to the level of light which penetrates the covering.

Much of the circuit shown in Fig. 4 corresponds to the circuit of Fig. 2 and like components have been given the same reference numerals. The lower branch of the Fig. 4
120 circuit, added to develop an alarm indication when the probe is shielded from its light source, functions in a manner generally similar to the upper branch.

Light received at the top of probe housing 301 is conveyed via fibre-optic bundle 300 within conduit 302 to an optical detector
130 303.

The circle identified by reference number 304 represents a receptacle which receives and engages the free end of conduit 302.

Optical detector 303 is connected to a
5 — 12 volt supply. A circuit change produced by a change in the conductivity of optical detector 303 when energized by light from the fibre-optic bundle is coupled to the inverting input of an amplifier 305, the non-inverting input of which is held at ground, i.e., it is earthed. Amplifier 305 is arranged with a
10 resistor 306 in a feedback configuration to the inverting input. Amplifier 305 preferably is similar in construction and operation to amplifier 204.

The output of amplifier 305 is coupled to the inverting input of a comparator-amplifier 309 which functions as a threshold circuit. The non-inverting input of amplifier 309 is
20 coupled to the central point of a voltage divider comprising resistors 307 and 308 connected between a + 12 volt supply and ground. With this arrangement, a signal at the inverting input of amplifier 306 will drive the amplifier output negative. This corresponds to light being detected by optical detector 303 which indicates that the probe is not covered and operating as expected. When the amplitude of the signal at the inverting input of
30 amplifier 309 falls below the threshold voltage established by divider 307 and 308, amplifier 309 operates to develop a positive output signal. This corresponds to little, if any, light being detected by optical detector
35 303 which indicates the the probe is covered or shielded from light. The threshold voltage at the junction of resistors 307 and 308 is set to represent a predetermined light level corresponding to the level of light impinging upon the end of fibre-optic bundle 300 when the
40 probe is uncovered. This threshold voltage may be set so that more than only a slight decrease in light level impinging upon the top surface of the probe is required to operate amplifier 309. The setting of resistor 308 is determined by the degree of decrease in light level for which it is desired to set off the alarm. Amplifier 309 preferably is similar in construction and operation to amplifier 206.

The output of comparator-amplifier 206 is coupled to the base of transistor 209 through a diode 212 and a resistor 213. The output of comparator-amplifier 309 is coupled to the base of transistor 209 through a diode 212
55 and a resistor 313. The arrangement is such that when either or both comparator-amplifier 206 and comparator-amplifier 309 develop a positive output signal, transistor 209 conducts and light emitting diode 210 is energized. In particular, amplifier 309 develops a positive
60 output signal whenever the probe is covered and the signal at the inverting input to amplifier 306 is below the threshold amplitude.

Thus, regardless of the output from amplifier
65 206, light-emitting diode 210 will be ener-

gized whenever the probe is covered. If the probe remains uncovered, but becomes dislodged from the body, an input current increase to the non-inverting input of amplifier
70 206 will produce an output which causes light-emitting diode 210 to become energized. Whether the alarm is set off because of probe dislodgement or probe covering, the system succeeds in catching the attention of someone
75 who can determine which of the two possibilities caused the alarm.

Although the invention, as described, contemplates the detection of ambient light, detectors which are selectively responsive to
80 only a portion of the light spectrum (e.g. infra-red) may be employed and, likewise, the radiation source may be of a more narrow bandwidth.

As stated previously, the present invention
85 has broader application than a skin contact temperature probe. The invention may be applied to other body surface probes which monitor or control other body functions or to probes which penetrate the body. For example, the dislodgement or partial withdrawal of
90 an intravenous feed needle, designed to have a contact surface, may be detected by incorporating the principles of the present invention.

While the embodiments of the probe illustrated in Figs. 1a, 1b and 3 show the use of fibre-optic bundles which transmit light to a distant alarm circuit at which photosensors convert the light to electrical signals, other
95 electro-optical techniques may be employed in practicing the present invention. For example, photocells may be located in the probe contact surface and in the upper housing surface to receive the light and develop electrical
100 signals which are transmitted to the distant alarm circuit.

The foregoing has set forth exemplary and preferred embodiments of the present invention. It will be understood, however, that
110 numerous alternative embodiments will occur to those of ordinary skill in the art without departure from the spirit or scope of the present invention.

115 CLAIMS

1. Apparatus for sensing probe dislodgement comprising a probe housing having a contact surface adapted for contact with a body; transducer means having a radiation
120 receiving portion located in said contact surface for sensing an increased radiation level impinging upon said contact surface when said probe housing is dislodged from said body and said contact surface is exposed to
125 said increased radiation level, and for developing a radiation signal representative of the radiation level impinging upon said contact surface; means for supplying a threshold signal representative of a predetermined radiation
130 level less than said increased radiation

level impinging upon said contact surface when said probe is dislodged from said body, and alarm means responsive to said radiation signal and said threshold signal for developing an indication when said radiation level impinging upon said contact surface exceeds said predetermined radiation level.

2. Apparatus according to Claim 1 wherein said predetermined radiation level corresponds to the level of background radiation reaching said radiation receiving portion when said contact surface is in contact with said body.

3. Apparatus according to Claim 1 or 2 wherein said alarm means includes a light-emitting device which is energized when said radiation level impinging upon said contact surface exceeds said predetermined level.

4. Apparatus according to Claim 1 wherein said transducer means include light-responsive means for sensing light impinging upon said contact surface and developing a light signal representative of the light level impinging upon said contact surface.

5. Apparatus according to Claim 4 wherein said light responsive means include a fibre-optic bundle having an input end in said contact surface and an output end distant from said contact surface, and a photo-detector positioned at said output end of said fibre-optic bundle and responsive to light transmitted from said contact surface by said fibre-optic bundle.

6. Apparatus according to Claim 1 wherein said apparatus also includes a thermistor for sensing the temperature of said body and developing a signal representative of said temperature.

7. A probe for sensing a body function comprising a probe housing having a contact surface arranged to contact a body; a sensor located in said contact surface and responsive to said body function; radiation receiving means located in said contact surface for sensing an increased radiation level impinging upon said contact surface when said probe housing is dislodged from said body and said contact surface is exposed to said increased radiation level, and means emanating from said housing for transmitting the outputs of said sensor and said radiation receiving means to a distant location.

8. A probe according to Claim 7 wherein said sensor is a thermistor which develops a signal representative of the temperature of said body and said transmitting means includes an electrical connection for conducting said signal to said distant location.

9. A probe according to Claim 7 or 8 wherein said transmitting means includes a fibre-optic bundle which transmits said radiation impinging upon said contact surface to said distant location.

10. Apparatus for indicating the dislodgement of an article from a body surface, said

apparatus comprising first transducer means having a radiation receiving portion located in a contact surface of said article adapted for contact with said body surface for sensing an increased radiation level impinging upon said contact surface when said article is dislodged from said body surface and said contact surface is exposed to said increased radiation level, and for developing a first radiation signal representative of the radiation level impinging upon said contact surface; second transducer means having a radiation receiving portion located in a second surface of said article removed from said contact surface for sensing a decreased radiation level impinging upon said second surface when said article is covered and said second surface is exposed to said decreased radiation level, and for developing a second radiation signal representative of the radiation level impinging upon said second surface; means for supplying a first threshold signal representative of a first predetermined radiation level less than said increased radiation level impinging upon said contact surface when said article is dislodged from said body; means for supplying a second threshold signal representative of a second predetermined radiation level greater than said decreased radiation level impinging upon said second surface when said article is covered, and alarm means responsive to said first and second radiation signals and said first and second threshold signals for developing an indication where said radiation level impinging upon said contact surface exceeds said predetermined first radiation level or said radiation level impinging upon said second surface falls below said predetermined second radiation level.

11. Apparatus according to Claim 10 wherein said predetermined first radiation level corresponds to the level of background radiation reaching said radiation receiving portion of said first transducer means and said predetermined second radiation level corresponds to the level of radiation impinging upon said second surface when said article is uncovered.

12. Apparatus according to Claim 11 wherein said alarm means include a light-emitting device which is energized when said radiation level impinging upon said contact surface exceeds said background radiation or said radiation level impinging upon said second surface falls below the level of radiation impinging upon said second surface when said article is uncovered.

13. Apparatus according to Claim 12 wherein said second surface is on the opposite side of said article from said contact surface.

14. Apparatus according to Claim 13 wherein said first and second transducer means include light-responsive means for sensing light impinging upon said contact

surface and said second surface.

15. Apparatus according to Claim 14 wherein said first transducer means includes a first fibre-optic bundle having an input end on
5 said contact surface and an output end distant from said contact surface and a first photo-detector positioned at said output end of said first fibre-optic bundle and responsive to light transmitted from said contact surface by said
10 first fibre-optic bundle; and said second transducer means includes a second fibre-optic bundle having an input end in said second surface and an output end distant from said second surface and a second photo-detector
15 positioned at said output end of said second fibre-optic bundle and responsive to light transmitted from said second surface by said second fibre-optic bundle.

16. A probe for sensing a body function
20 comprising a probe housing having a contact surface arranged to contact a body and a second surface spaced from said contact surface; a sensor located in said contact surface and responsive to said body function; first
25 radiation receiving means located in said contact surface for sensing an increased radiation level impinging upon said contact surface when said probe housing is dislodged from said body and said contact surface is exposed
30 to said increased radiation level; second radiation receiving means located in said second surface for sensing a decreased radiation level impinging upon said second surface when said article is covered and said second surface
35 is exposed to said decreased radiation level; and means emanating from said housing for transmitting the outputs of said sensor and said first and second radiation receiving means to a distant location.

40 17. A probe according to Claim 16 wherein said sensor is a thermistor which develops a signal representative of the temperature of said body and said transmitting means include an electrical connection for
45 conducting said signal to said distant location.

18. A probe according to Claim 16 or 17 wherein said transmitting means includes first and second fibre-optic bundles which transmit
50 said radiation impinging upon said contact surface and said second surface to said distant location.

19. Apparatus for sensing skin contact probe dislodgement comprising housing means defining a skin contact surface for said
55 probe; photo-receptive means located on said skin contact surface of said housing means; alarm means, energized by reception by said photo-receptive means of light, having an intensity exceeding a predetermined level, said
60 alarm means being placed remotely from said housing means, and photo-transmitting means extending out from said housing means for connecting said housing means, photo-receptive means and said alarm means.

65 20. Apparatus as claimed in Claim 19

wherein said alarm means comprises a transducer means for converting light, received from said photo-receptive means, to an electrical signal, and circuit means for detecting said
70 electrical signal and for displaying a condition corresponding to a change in surface contact.

21. Apparatus as claimed in Claim 20 wherein said photo-receptive means comprises a fibre-optic bundle extending to said transducer from said photo-receptive means, and
75 an opaque conduit surrounding said fibre-optic bundle.

22. Apparatus as claimed in Claim 21 wherein said photo-receptive means includes
80 an optically polished fibre-optic end.

23. Apparatus as claimed in Claim 22 wherein said circuit means includes a threshold detection circuit, responsive to said transducer electrical signal, said threshold corresponding to the level of background light
85 reaching said photo-receptive means when there is intimate contact between the patient's skin and said skin contact surface, and light emitting alarm means energized by said
90 threshold detection circuit.

24. Skin-contacting or other body-contacting probe and a circuit for detecting probe dislodgement substantially as described herein with reference to Figs. 1a and 1b and Fig. 2
95 of the accompanying drawings.

25. Skin-contacting or other body-contacting probe and a circuit for detecting probe dislodgement substantially as described herein with reference to Figs. 3 and 4 of the accompanying drawings.
100

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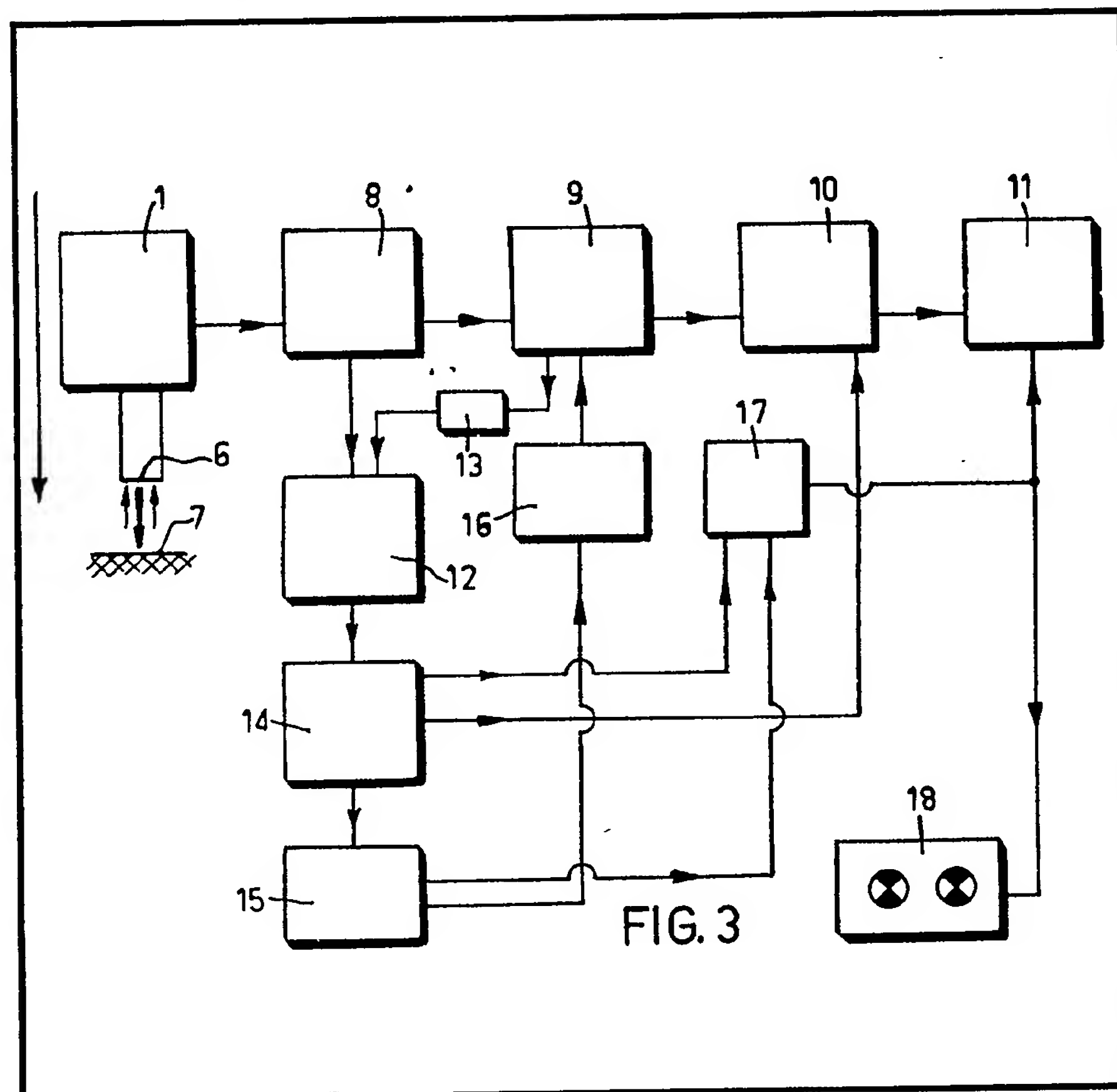
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(54) Process and apparatus for making a numerical determination of the colour, or of a colour change of an object

(57) A coaxial optical fibre bundle assembly 6, carrying emitted light from a light source and receiving light which has been returned by an object illuminated from said light source, is moved towards the object 7 to cause the intensity of the received light, as detected by a photo transistor in light emitter-receiver unit 1, to attain maximum value which is amplified and held as a display on digital voltmeter 11. Comparison of the held value with the corresponding held maximum value resulting from a similar determination made of either a different object or the same object after a colour change can thus be made on a numerical basis.



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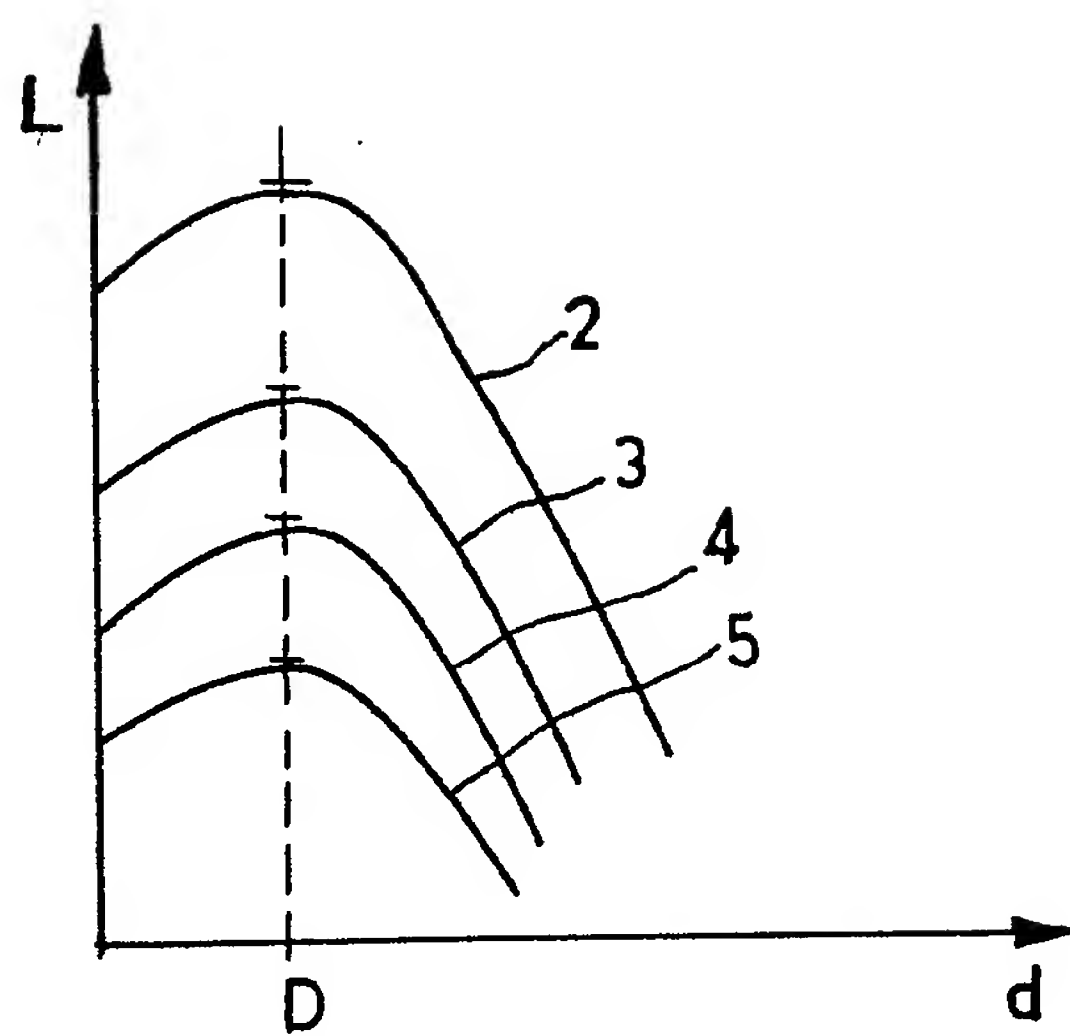


FIG. 1

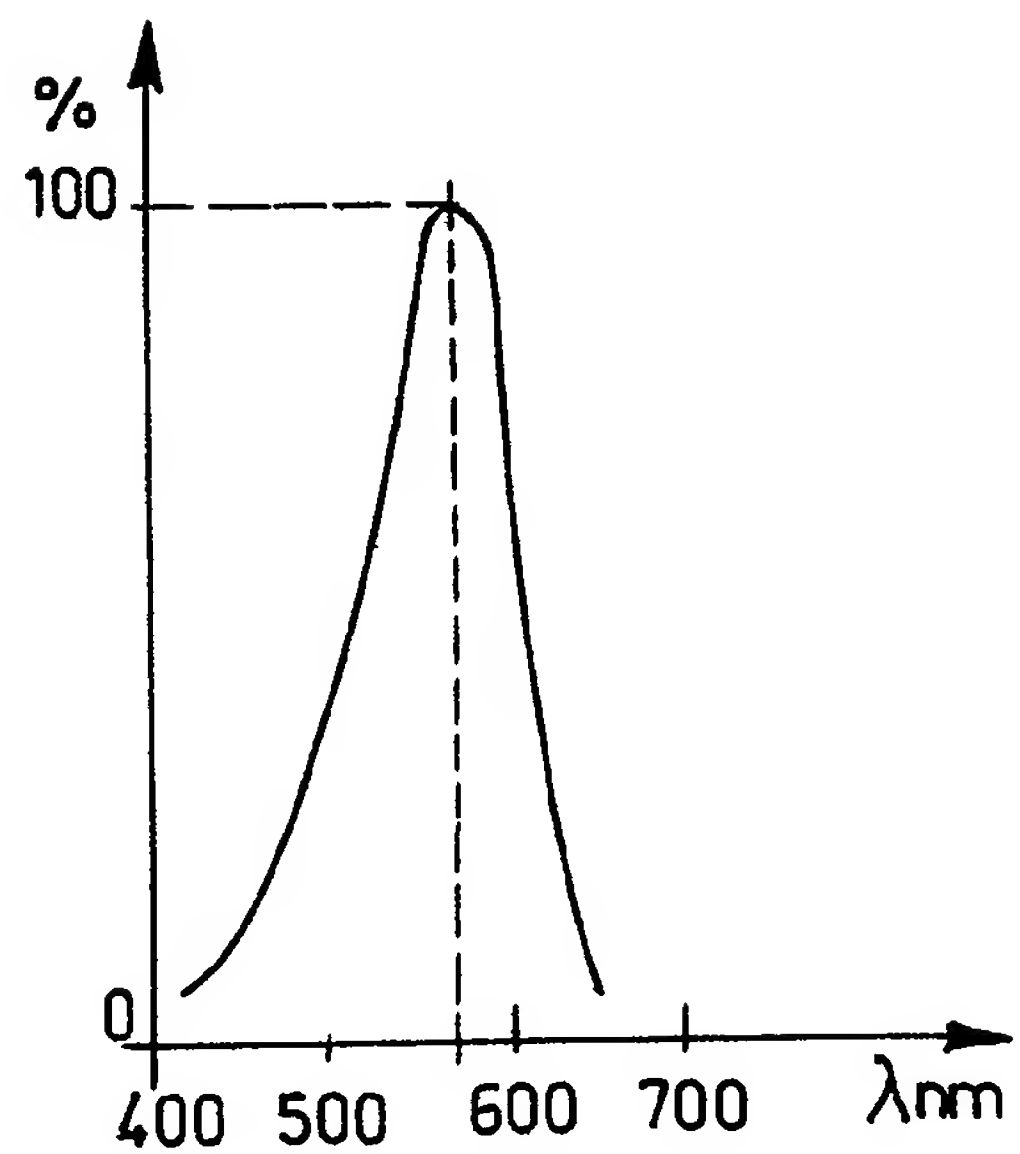


FIG. 2

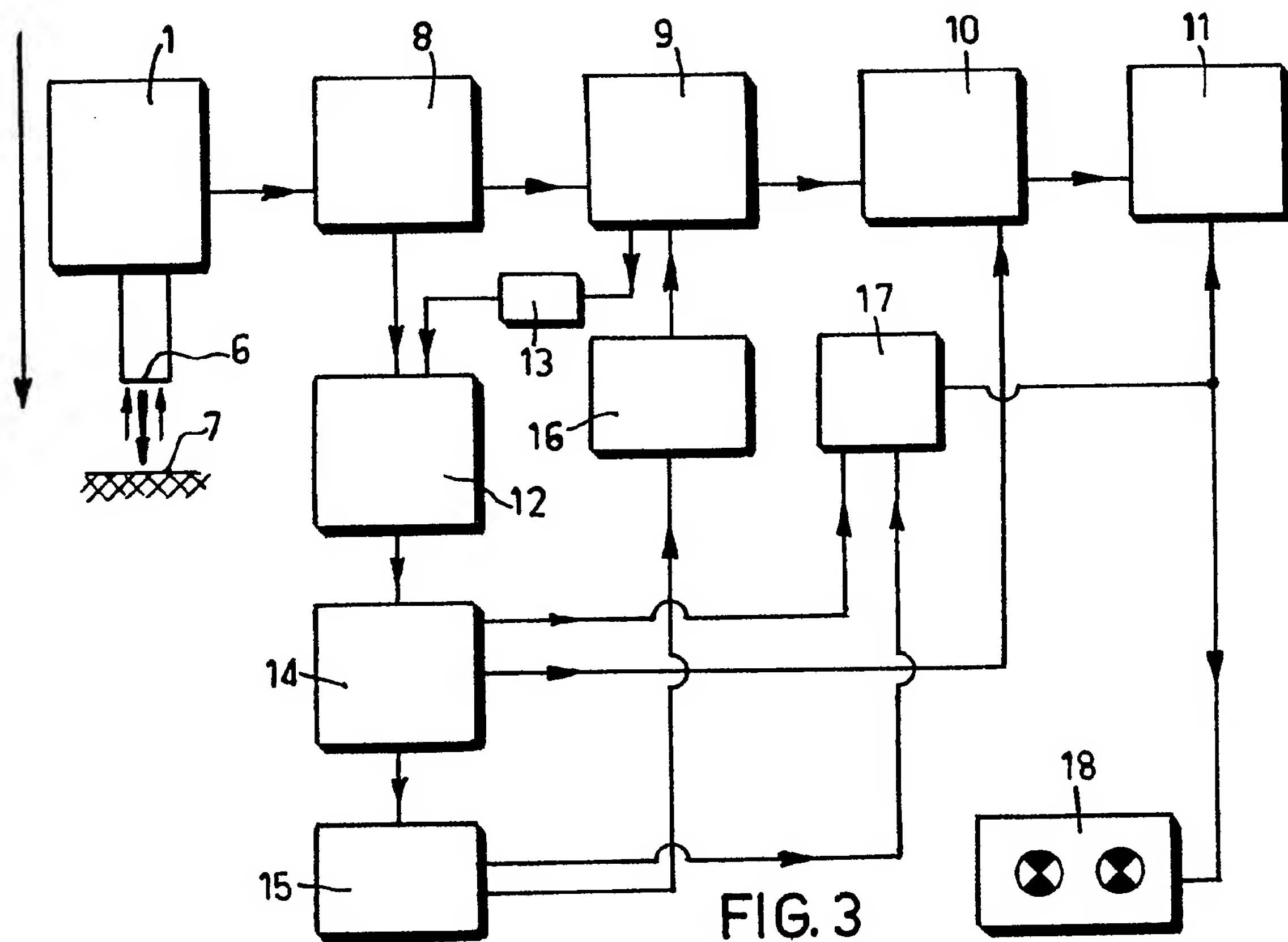


FIG. 3

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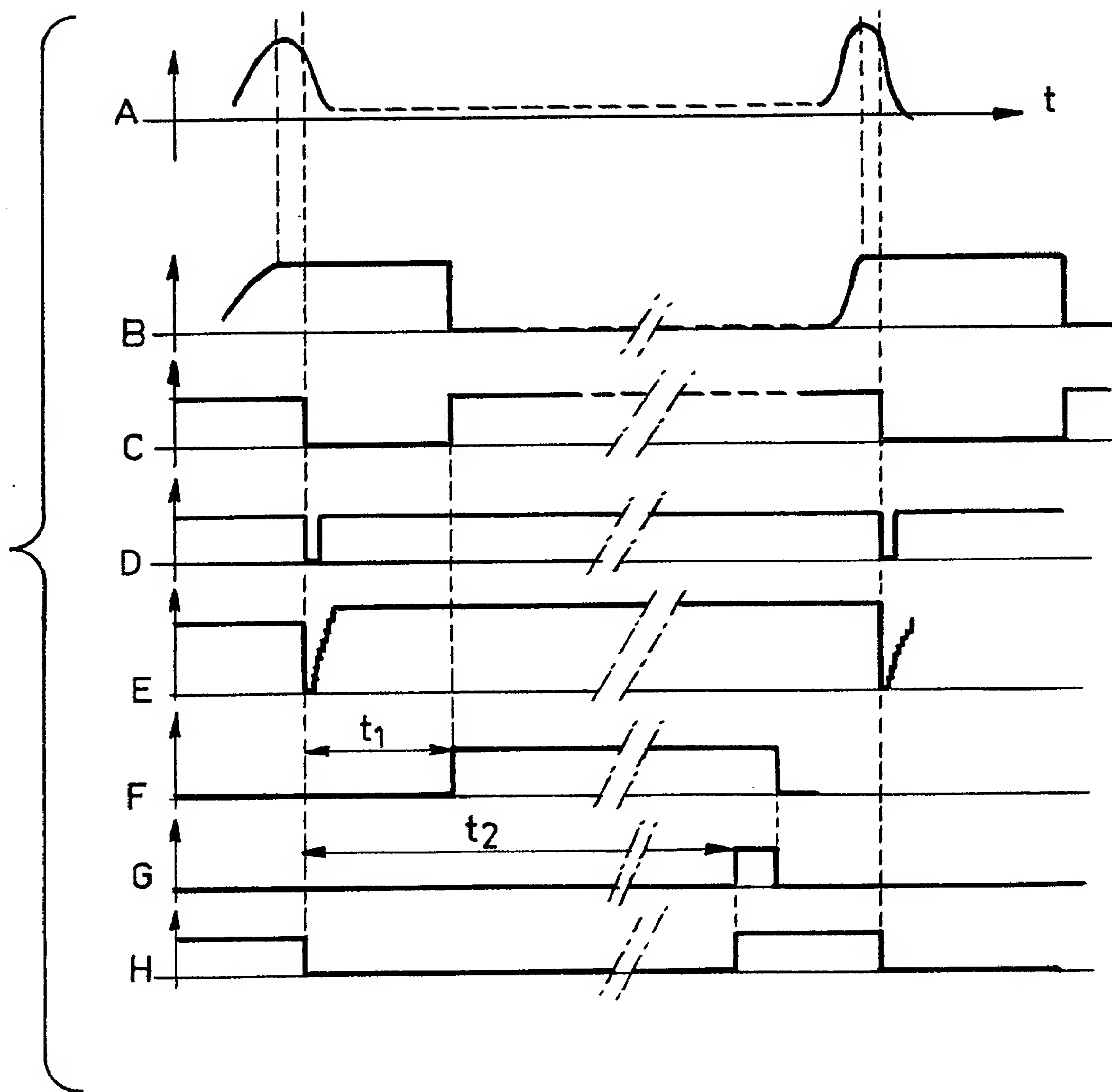


FIG. 4

SPECIFICATION

5 **Process and apparatus for making a numerical determination of the colour, or of a colour change, of an object**

The present invention relates to an apparatus and a process for carrying out a numerical determination of the colour, or of a colour change, of an object. More particularly the process and apparatus of the present invention do not require any contact with the object being investigated.

It is known that it is often desirable to allocate a numerical value to the colour, or the colour change of an object. Usually, the observation of an object by the human eye makes it possible to give qualitative information but this has two drawbacks. On the one hand, if the qualitative information is converted into quantitative data by an observer, the numerical value depends considerably on the judgement of the particular observer and may vary from one observer to another. Moreover, the human eye has difficulties in observation to allocate an indication corresponding strictly to the state of a restricted zone without taking into account the colour impression supplied by the surroundings of the observed zone; the surroundings are always taken into consideration so that the results of the qualitative observation of a zone depend largely on the contrasts supplied by the surrounding zones. This phenomenon is particularly evident when one is examining, for instance, the state of redness of human skin, particularly following solar radiation. The observation is affected not only by the intensity of the lighting but also by the background colour of the irradiated skin and by the extent of the contrast between the normal skin and the reddened skin.

It is, moreover, known that any apparatus permitting the numerical determination of an object's colour should be able to function without having to contact the object in the zone investigated. In fact, certain objects to be observed may be moving, or hot, or radioactive, and therefore they must not come into contact with the apparatus. Other objects may change their colour if they are subjected to pressure as is for instance, the case, with irradiated skin where contact pressure produces whitening due to closing of the capillaries. This colour change is also the case with liquid crystals which change colour according to the pressure to which they are subjected.

Now, in the present state of technology, a numerical determination of a colour is obtained by successively illuminating the object by luminous emissions corresponding to different wave lengths and measuring in each case the light returned by the object by way of reflection and diffusion towards a receiver.

65 This technique essentially requires the maintenance of a strictly determined distance between the measuring apparatus and the object subjected to observation, so in the case of soft materials it is necessary to bring the materials

70 into contact with a glass plate or slide. It follows that a pressure which, even though of small magnitude, is not zero, is exerted on the objects to be observed and that this method is not suitable in the case of materials which change colour according to pressure or of those which are moving, hot, or radioactive. Moreover, in this known state of technology, the result of the measurement depends on the surrounding lighting and, in order to become independent thereof, it is not possible to use a pulsed source since in order to obtain a sufficient quantity of light reflected and diffused by the object it is necessary to use a powerful source. It will thus be seen that the present state of technology does not provide an apparatus which is capable of numerically recording a colour or a colour modification of an object in a simple and reproducible manner without contact with the said object.

90 The object of the present invention is to provide a process and an apparatus facilitating the numeral determination of a colour, or a colour change, of an object which do not require contact with the said object. Strictly speaking, the apparatus does not make it possible to obtain an absolute numerical measurement corresponding to a colour, but it makes it possible to make a numerical determination of a colour or a colour change which determination can be compared with determinations made by using other similar apparatus. With such an apparatus, it is for instance possible to study the effects of vasoconstrictors by examining the whitening of a human skin; it is also possible to study the extent of an erythema affecting a skin zone by comparing the measurement obtained on the said zone with a corresponding measurement obtained on a normal skin zone. One may, moreover, exert pressure on a reddened skin to close the capillaries and to whiten the skin zone concerned, then release the applied pressure and study the kinetics of the return of the skin to its original colour. The apparatus according to the invention thus finds a great number of applications and this all the more so, since its operation is extremely simple.

Accordingly one aspect of the present invention provides apparatus for making a numerical determination of the colour, or of a colour change, of an object, the apparatus comprising: a source of light to irradiate the object; a photo transducer to pick up the light returned by the object; optical fibre receiver means to direct the light returned by the object to the said photo transducer, the said optical fibre receiver means having an end displaceable substantially perpendicularly to the object being investigated to obtain the desired determination; optical fibre emitter

means to direct the emission of said light source to a said object being investigated; said optical fibre emitter means and optical fibre receiver means being fixed together for
 5 conjoint movement towards and away from a said object being investigated; a detection circuit for determining the value of the maximum of the signal supplied by the photo receiver during the displacement of the said
 10 end of the optical fibre receiver means; and a display unit responsive to said detection circuit for displaying information according to the determination made.

Another aspect of the invention provides a
 15 process for making a numerical determination of the colour, or of a change in colour, of an object comprising taking an apparatus according to the first aspect, moving said coaxial ends of said first and second optical fibre
 20 bundles towards said object while receiving the light from said light source returned from the said object, processing the output signal of said photo receiver using said detector circuit, and displaying the output of said de-
 25 tector circuit using said display unit.

The principle of the invention lies in sending a luminous emission on to the object to be investigated, receiving the light returned by the object and determining the maximum value of the reception as the receiving surface of the object subjected to the luminous emission is approached. When the emitting and receiving surfaces are the ends of optical fibre bundles, the intensity of the light re-
 35 transmitted by the object generally passes through a maximum value if the two surfaces of the object are simultaneously brought near each other. The distance corresponding to the attainment of this maximum value only de-
 40 pends on the geometry of the receiver system and therefore if it is the said maximum value itself which is determined, the measurement of the retransmitted light is always effected at the same distance from the object. The result
 45 is thus independent of any constraint imposed by the apparatuses of present-day technology.

The measurement assembly may have a spectral sensitivity corresponding to the sensitivity of the human eye; it is possible to effect
 50 correlations between the measurements effected and direct visual observations. If the filter used allows a light to be emitted having a wave length corresponding to the object's colour, the object will return a maximum
 55 quantity of light to the receiver. On the other hand, the greater the difference of the object's colour from the medium wave length of the light emission used, the more the quantity of light returned to the receiver by the object will
 60 be reduced. It will thus be seen that the intensity of the maximum value of the output signal from the photo transducer essentially depends on the colour of the object for a luminous emission having any given spectral
 65 characteristics. If one examines, with the

same light emission, two differently coloured zones of the same object or the same zone of the object after its colour has been modified and if the results of the two measurements
 70 are compared, one obtains a numerical indication of the colour modification of the object which is practically independent of the light emission used.

In a preferred embodiment of the apparatus, the said first and second optical fibre bundles have their ends coaxial and in the same plane substantially parallel to the object, it being possible to cause the said ends to approach the object substantially perpendicu-
 75 larly to the object in order to effect the required determination; the receiver picks up from the object reflected light filtered through an optical filter whose wave lengths are distributed around a medium wave length ap-
 80 proximating to the wave length corresponding to the object's normal unmodified colour; provision may also be made for the light emitter to comprise an optical filter emitting a light whose spectral distribution approximates to
 85 that corresponding to the sensitivity of the human eye; the signal processing detector circuit comprises a peak detector comprising an analogue memory; the peak detector is connected to the input of an analogue/digital
 90 and digital/analogue converter whose output feeds the display unit; the display unit comprises a volt meter; a signal proportional to the output signal of the peak detector (the proportionality coefficient being less than 1) is
 95 compared in a comparator with the output signal of the photo transducer and the comparator initiates, at the moment the two compared signals are equal, resetting to zero of the said converter as well as the start of a first
 100 timed period at the end of which, the peak detector is reset to zero and a second timed period is started, at the end of which, the display unit is reset to zero.

The apparatus according to the invention
 110 has the advantage of being extremely simple to handle since it suffices to bring the optical emitter-receiver fibre bundles near the object to be investigated until they are in contact with the object or in the immediate proximity
 115 of this contact if such contact must be avoided. In any case, whether contact with the object is established or not, the measurement is effected before the said contact takes place so that the measurement is not dis-
 120 turbed by any possible disturbing effect of the contact of the optical fibres on the object.

The result of the measurement is numerically displayed on a digital voltmeter which is automatically reset to zero after a certain
 125 display period so that it is possible to effect a great number of measurements in an extremely short time. Moreover, it should be observed that the measurement effected only concerns an extremely limited zone of the
 130 object investigated and that it is completely

independent of the colouration of the object's surrounding zones: thus one is no longer dependent on the ability of the human eye to take into account the colourimetric data of the surroundings of the zone subjected to observation. The apparatus supplies a colour determination for a given filtering of the returned luminous emission but of course, the numerical value obtained is modified if the spectral characteristics of the light emission or of the filtering are changed. On the other hand, the results which can be obtained by the apparatus are much more independent of the luminous emission if a colour modification is studied, that is to say if one effects a measurement on a zone of the object and compares it with a similar measurement made on the same object with the same luminous emission, either at the same point or at a different point after the colour of the observed zone has been modified.

In the special case where the apparatus is used for an investigation of the skin, it is preferable to use an optical filter giving a maximum intensity in yellow and whose total range is in the visible spectrum. In these conditions, the maximum response of the apparatus is obtained by examining a yellow object and the examination of a normal skin allows approximately 70% to 80% of the maximum response to be obtained. If erythemas of the skin are studied, it will be seen that the redder the skin the lower the numerical value obtained, and for a pronounced erythema, the reception value of the sensor is approximately 10 to 20% of the maximum response of the said sensor.

In order that the present invention may more readily be understood, an embodiment represented on the accompanying drawing will now be described, by way of a purely illustrative and non-restrictive example. In these drawings:

Figure 1 represents the curves giving luminous intensity L returned by the object (and picked up by the photo receiver) for a given luminous emission in relation to distance d between the object and the end of the optical fibres of the emitter-receiver assembly used in the apparatus according to the invention, each one of these curves corresponding to a different colour of the object subjected to examination;

Figure 2 represents the distribution of the spectrum obtained by means of the optical filter which is interposed ahead of the photo receiver of the preferred embodiment of apparatus;

Figure 3 is a block diagram of the electronic circuit processing the output signal of the photo receiver of the apparatus according to the invention; and

Figure 4 represents the formation, with respect to time, of the signal at various points of the block diagram of Fig. 3.

Referring to the drawings, there will be seen the emitter-receiver unit 1 of the apparatus according to the invention. Unit 1 comprises a light bulb which emits a white light, and an optical filter whose spectral characteristics are represented by the curve of Fig. 2. The luminous beam is sent into an emitter optical fibre bundle which constitutes at its end surface 6 the sheath of a second optical fibre bundle coaxial with the first. The two coaxial, optical fibre bundles have a common end surface 6, the second bundle serving as a receiver intended to receive the luminous flux returned by the object which is subjected to the incident flux originating from the emitter optical fibre bundle. The second optical fibre bundle or receiver bundle is connected to a photo transistor which constitutes the photo transducer of the apparatus according to the invention. The emitter-receiver unit 1 is not described in greater detail because it is marketed by the Company "SKAN-A-MATIC" of the United States of America under reference number "S 35203", with the optical filter.

In view of the geometry of the optical fibre bundles, the light emitted by the peripheral emitter fibre bundle and returned by the object only enters the optical receiver fibre bundle under certain angular pre-conditions so that the light intensity detected by the photo transistor which is connected to the receiver fibre bundle passes through a maximum when the common ends of the emitter and receiver fibre bundles are located at a distance D (Fig. 1) from the object being investigated.

Fig. 1 shows the shape of the curve indicating light intensity L determined by the photo receiver in relation to distance d from the front end surface 6 of the optical fibre bundles in relation to the object. Distance D corresponding to the maximum value of the light reception is always the same for a given emitter-receiver unit 1.

The different curves represented on Fig. 2 show the light intensities received by the photo transistor, according to the colour of the object which is presented in front of the end surface 6 of the emitter-receiver bundle assembly. If this object has a colour whose wave length corresponds to the maximum of the spectral distribution of the particular filter selected, the light intensity detected by the photo transistor is the maximum one which corresponds to curve 2 of Fig. 1. On the other hand, the more the object's colour differs from the dominant colour of the filter the lower is the light intensity detected by the photo transistor; curves 3, 4 and 5 show the light reception levels for orange, orange-red and red objects whilst curve 2 corresponds to a yellow object. As will be clear from the wave lengths indicated in Fig. 2, the filter is centred on yellow.

The values of the maxima of curves 2, 3, 4 and 5 therefore constitute a determination of

the colour of the object which is presented opposite the end surface 6 of the coaxial optical fibre bundles. Of course, the numerical values corresponding to these maxima depend essentially on the nature of the filter which has been used for their determination. On the other hand, if a given object changes its colour and if the same apparatus is used to effect measurements both before and after the colour modification, comparison of the results of the two measurements will give a determination of the colour modification which colour modification determination depends to a far lesser degree on the nature of the light emission used.

To effect the measurement, it is sufficient to bring the end surface 6 of the coaxial optical fibres near to the object, either right up to contact with the object if there is nothing prohibiting contact or up to a proximity of a few millimetres if contact with the object must be avoided. In the course of this approach, the photo transistor output signal passes through a maximum at the moment when the end of the optical fibres is at a distance D from the object. As will be described in detail below, the apparatus allows the measurement to be effected at the precise moment when the distance d passes the distance value D .

This technique is particularly worthwhile if it is intended to study erythemas of the skin, because in that case it is possible to bring the end surfaces of the optical fibres right up to contact with the skin although this contact will cause the skin to whiten and will therefore modify the colour of the observed zone since the measurement is taken at a moment before the contact has been effected and when, therefore, the skin still retains its unmodified colour.

In Fig. 3, there has been shown the block diagram of the electronic circuit which allows the measurement to be obtained at the moment when end surface 6 of the optical fibre bundles is located at distance D from object 7 being investigated. The output signal of the photo transistor of the emitter-receiver unit 1 is sent to an amplifier 8 whose output is applied as input to a peak detector 9. In the conventional manner, the peak detector 9 comprises a capacitor having a sizable time constant, about 10 seconds for instance, since this capacitor only discharges very slowly.

The output signal of amplifier 8 is represented on line A of Fig. 4 for the part which corresponds to the passage of the photo transducer output through the maximum, i.e. at a moment when end surface 6 of the optical fibre bundle is at a distance D from object 7. The signal supplied at the output of peak detector 9 is represented on line B of Fig. 4.

This signal is directed to an analogue/digital and digital/analogue converter 10. When reset to zero, the converter 10 charges a memory at the frequency of its internal timer

and converts the memory content into an analogue output voltage and it compares the output voltage with the input voltage; the charging of the digital memory continues until the output voltage is equal to the input voltage; at this moment, converter 10 is blocked until it receives a reset pulse to cause it to reset to zero. The output voltage supplied by converter 10 is applied to a digital voltmeter 11 which constitutes the display unit.

The output from amplifier 8 is also applied to a comparator 12 whose second input receives the voltage corresponding to the output of peak detector 9 reduced by a proportionality coefficient of less than 1 derived from a divider bridge 13. In this embodiment, the proportionality coefficient selected is 0.75. The output of comparator 12 is thus a binary signal which is at the higher level while the output voltage of amplifier 8 is higher than that supplied by divider bridge 13 and which changes over to a lower level as soon as the opposite occurs.

This binary signal from comparator 12 is represented on line C of Fig. 4. The descending front of the signal on line C therefore indicates that the maximum of the output signal of the photo transistor of unit 1 has been passed and one may therefore charge the converter 10 with the value stored in peak detector 9. The use of a proportionality coefficient of 0.75 by virtue of the divider bridge 13, makes it possible to avoid any possible interference effects.

The output of comparator 12 controls a monostable device 14 whose output signal is represented in line D of Fig. 4. The output signal of the monostable device 14 is applied to the converter 10 and constitutes the reset signal, resetting the converter to zero to allow the digital memory of the converter to be charged at its internal timer frequency, which charge is produced in 150 nano-seconds at most. As explained above, when the output voltage of converter 10 is equal to the input voltage, converter 10 becomes blocked so that the display on voltmeter 11 remains constant, this display having changed during the charging time of converter 10. The output signal of converter 10 has been represented on line E of Fig. 4 but in this representation, the charging time of the converter has been greatly exaggerated to make it visible in the drawing.

The monostable device 14 releases a timing circuit 15 which supplies two timed periods.

The first timed period is determined by a signal represented on line F of Fig. 4. At a time t_1 after the descending front of the pulse from the monostable device 14, the signal of the first timed period has a rising front which is directed to a transistor 16 arranged in parallel with the capacitor of peak detector 9. The first timed period signal thus produces the resetting to zero of the peak detector

output which does not affect the output of converter 10 since the converter has been blocked after completing its charging. The resetting to zero of the output of peak detector 9 also prompts change to the higher level of the output of comparator 12. In the example described, time t_1 is approximately 20 ms.

The second timed period signal is represented on line G of Fig. 4. This signal has a rising front at time t_2 after the descending front of the pulse produced by the monostable device 14. This rising front initiates by way of interface 17, the resetting to zero of the digital voltmeter 11, the output signal of interface 17 being represented on line H of Fig. 4. The second timed period signal constitutes a rectangular pulse and its descending front entails the resetting to zero of the signal relating to the first timed period. The signal supplied by interface 17 is reset to zero at the time of the descending front of the pulse supplied by monostable device 14. The signal supplied by interface 17 is therefore at its lower level during a timed period t_2 , and t_2 is chosen at the order of 20 seconds which allows the user of the apparatus to have the display of the measurement on digital voltmeter 11 at his disposal for 20 seconds. After these 20 seconds, the display of digital voltmeter 11 is reset to zero. An indicator device 18 is provided to indicate by one illuminated sign that the apparatus is in the measurement or reading off phase and by a different illuminated sign that the apparatus is on standby which makes it possible to effect a new measurement.

It will be seen that the apparatus which has just been described is simple to make so that its cost price is relatively limited. Moreover, it is very simple to use and the measurements effected can be taken very rapidly. The rapidity of these measurements makes it possible to study the kinetics of a change in colour which may for example extend over several minutes.

CLAIMS

1. Apparatus for making a numerical determination of the colour, or of a colour change, of an object, the apparatus comprising: a source of light to irradiate the object; a photo transducer to pick up the light returned by the object; optical fibre receiver means to direct the light returned by the object to the said photo transducer, the said optical fibre receiver means having an end displaceable substantially perpendicularly to the object being investigated to obtain the desired determination; optical fibre emitter means to direct the emission of said light source to said object being investigated; said optical fibre emitter means and optical fibre receiver means being fixed together for conjoint movement towards and away from a said object being investigated; a detection circuit for determining the

value of the maximum of the signal supplied by the photo receiver during the displacement of the said end of the optical fibre receiver means; and a display unit responsive to said detection circuit for displaying information according to the determination made.

2. Apparatus according to Claim 1, wherein said optical fibre emitter means and optical fibre receiver means comprise first and second optical fibre bundles having coaxial ends in the same plane substantially parallel to the object, the said ends being displaceable together substantially perpendicularly to the object to effect the desired determination.

3. Apparatus according to Claim 1 or 2, wherein the said photo transducer further comprises an optical filter.

4. Apparatus according to Claim 3, wherein said optical filter has a spectral distribution which approximates to that which corresponds to the sensitivity of the human eye.

5. Apparatus according to any one of Claims 1 to 4, wherein said detection circuit comprises a peak detector and an analogue memory.

6. Apparatus according to Claim 5, wherein said peak detector is connected to the input of an analogue/digital and digital/analogue converter whose output feeds said display unit.

7. Apparatus according to Claim 6, wherein said display unit comprises a voltmeter.

8. Apparatus according to Claim 7, wherein said voltmeter is a digital voltmeter.

9. Apparatus according to Claim 6, 7, or 8, including: means to obtain a signal proportional to the output signal of said peak detector, the proportionality coefficient being less than 1; and a comparator comparing the said proportional signal and the output signal of said photo transducer, wherein, as soon as the two compared signals are equal, said comparator initiates the resetting to zero of the converter as well as the start of a first timed period at the end of which there is produced both a resetting to zero of said peak detector and the commencement of a second timed period at the end of which said display unit is reset to zero.

10. Apparatus according to any one of Claims 1 to 9, which is usable for examining the skin, wherein the light emission is effected practically completely in the visible spectrum with a maximum in yellow.

11. Apparatus for making a numerical determination of the colour, or of a colour change, of an object, said apparatus being constructed and adapted to operate substantially as hereinbefore described with reference to the accompanying drawings.

12. A process for making a numerical determination of the colour, or of a change in colour, of an object, comprising taking an apparatus according to claim 1, moving said

coaxial ends of said first and second optical fibre bundles towards said object while receiving the light from said light source returned from the said object, processing the output signal of said photo receiver using said detector circuit, and displaying the output of said detector circuit using said display unit.

5 13. A process for making a numerical determination of the colour, or of a change in colour, of an object without contact with the object, comprising illuminating an object, moving a mobile light receiver means towards the illuminated object while picking up the light returned by said object, to cause the
10 output signal of the light receiver means to rise up to a maximum value, and processing said maximum value of the output signal to derive a numerical value proportional to said maximum value.

20 14. A process according to Claim 12 or 13, when carried out using an optical filter in the path of the said returned light picked up from the illuminated object, said optical filter having a medium wave length which approxi-
25 mates to the wave length corresponding to the normal unmodified colour of the object being investigated.

30 15. A process for making a numerical determination of the colour, or of a change in colour, of an object without contacting said object, such method being substantially as hereinbefore described with reference to the accompanying drawings.

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(54) Pump for pumping liquid

(57) A pump for pumping liquid devised for medical or surgical use operates on an Archimedean screw principle and comprises a flexible plastics tube (11) having a flexible central drive cable or rod (15) stretching between its ends. An operative end (12) contains a Archimedean screw pump element (14) having a helix angle between 30° and 45° and centrally positioned by a spider (16). The operative end (12) has a filter mesh (13) and can be used for pumping blood, urine or other body fluids for example. The pump does not produce a vacuum and so avoids suction effect on surrounding tissue and the entrainment of large quantities of air.

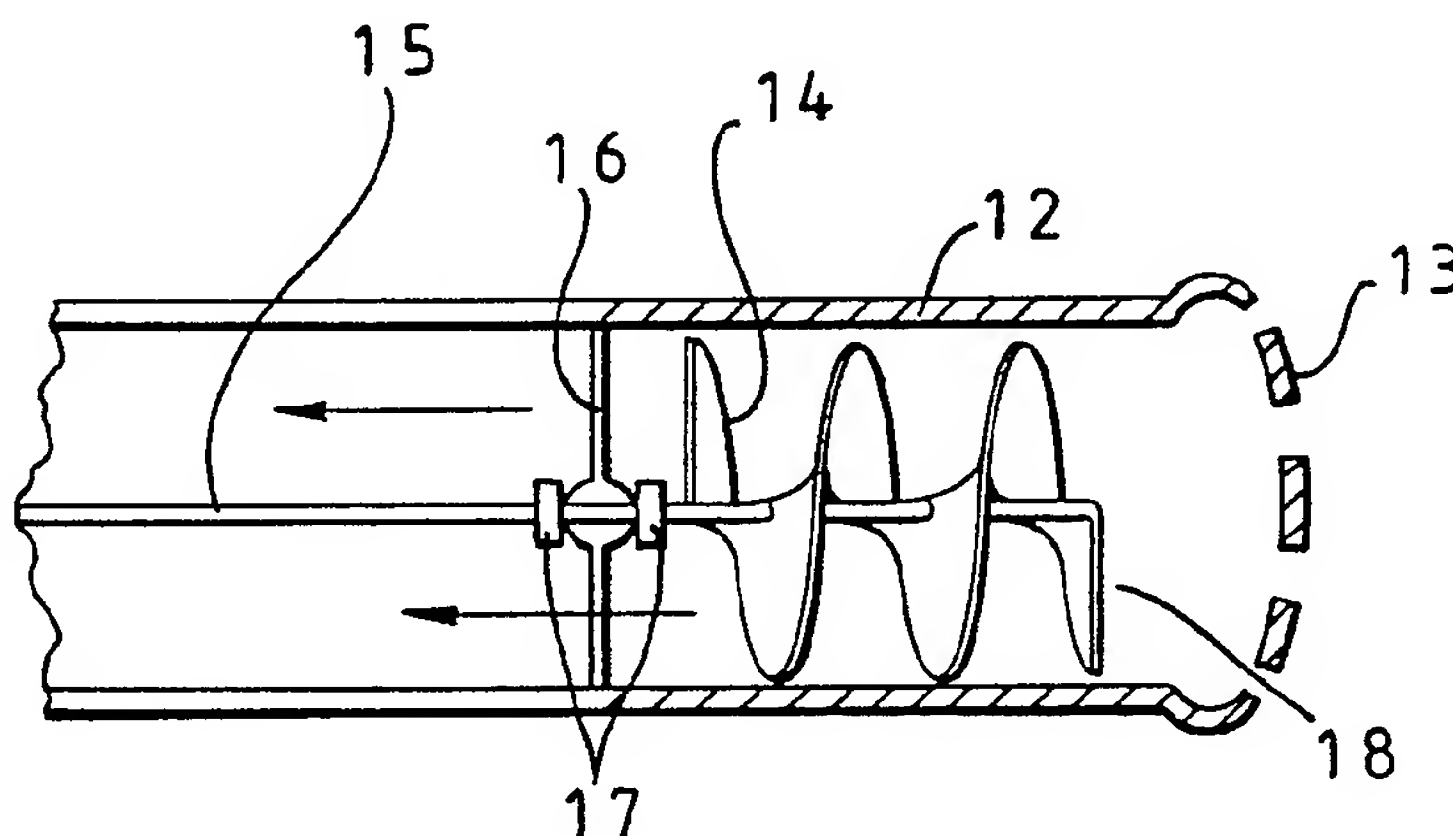
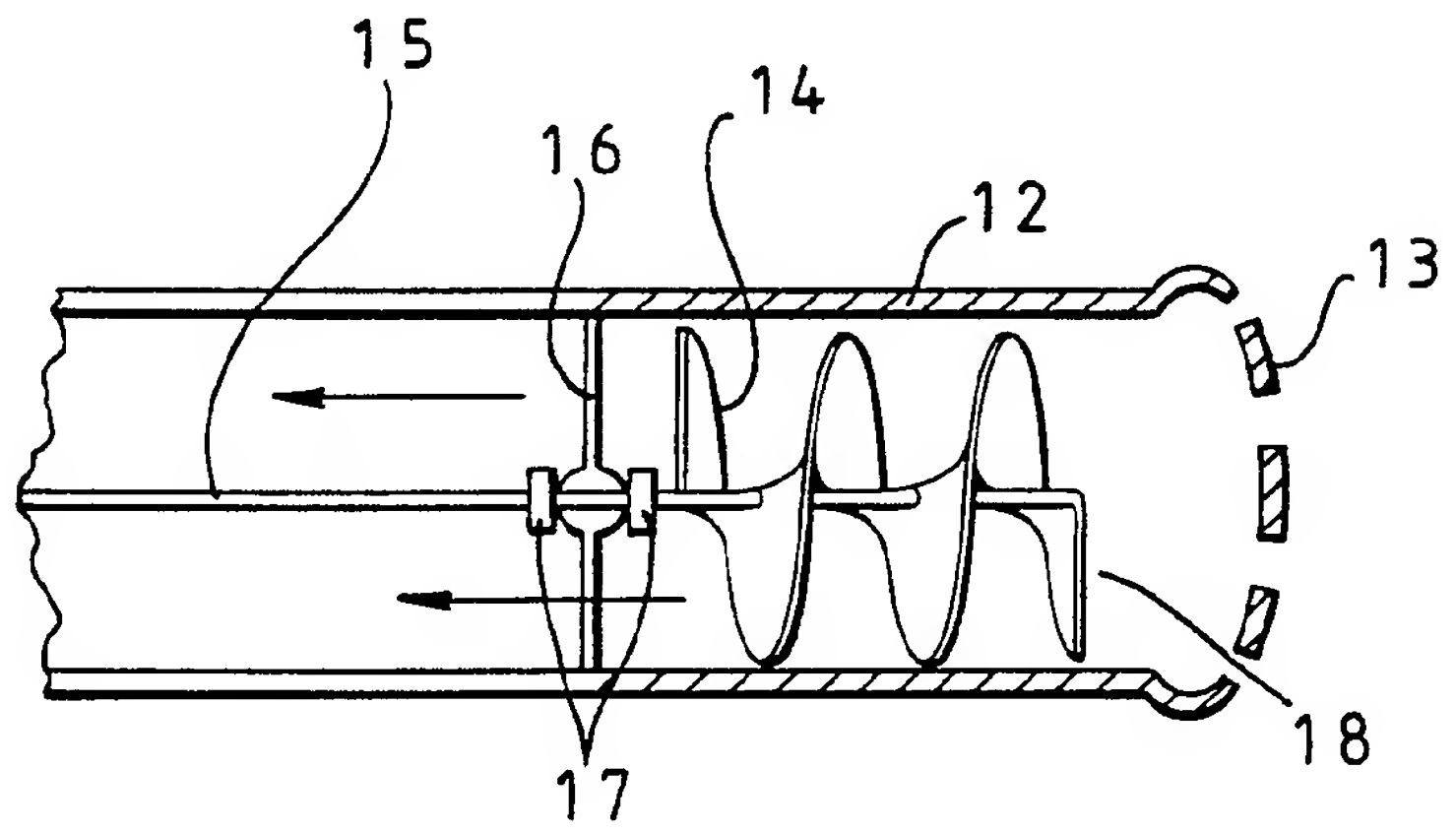
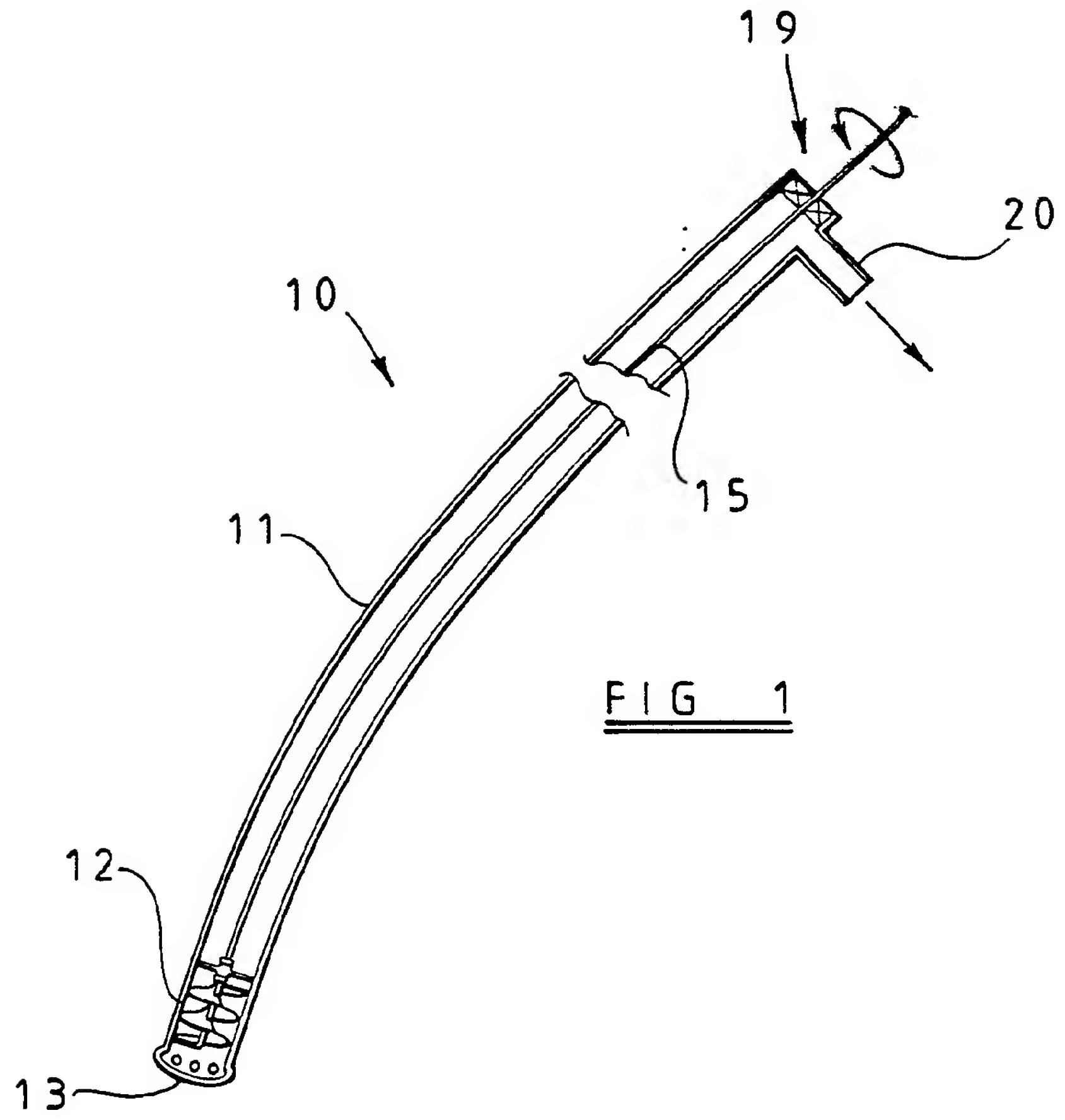


FIG 2



Title: Pump for Pumping Liquid

This invention relates to a pump for pumping liquid.

It was particularly devised for medical and surgical use but may find application in other fields.

In medicine and surgery there is often a requirement to pump body liquids for example blood, urine or saliva. Conventional aspiration equipment uses a partial vacuum to suck fluid into a tube to a collection vessel.

There are several disadvantages to this method, especially in the medical and surgical context. Firstly, the suction is noisy. When the liquid is partially or completely drained, neighbouring tissue may be sucked against the tube by the vacuum, causing unnecessary damage to such tissue. Air is continuously drawn through a suction aspiration system. In situations where the aspired fluid is reintroduced to the patient, there is a risk of bacteria from the surrounding atmosphere being drawn into the liquid and concentrated by the action of the suction pump.

It is an object of the present invention to provide a pump for pumping liquid which does not rely on the creation of a partial vacuum.

According to the invention there is provided a pump comprising a tube, a helical pump element sized to be a close running fit within the tube, journal means for rotatably mounting the helical pump element at an operative end of the tube, elongate drive means for the helical pump element disposed within the tube and outlet means for liquid.

The tube may be flexible throughout its length except at the operative end.

The helix may have an angle of between 30° and 45° .

The drive means may comprise a Bowden cable or a rotary drive rod.

The outlet means may be laterally disposed at a position between the ends of the flexible tube. The operative end of the tube may have a filter.

The invention will now be described in more detail by way of example only with reference to the accompanying drawings in which:

Figure 1 shows a pump embodying the invention

Figure 2 is an enlarged detail view of the operative end of the pump.

Referring to the drawings, a pump generally indicated at 10 comprises an elongate flexible tube 11 which is made from plastics material. An operative end portion 12 of the pump comprises a rigid plastics tube, shown in more detail in Figure 2.

A grid or mesh 13 covers the operative end.

A helical pump element 14 is mounted concentrically with the operative end 12 of the tube. The pump element 14 has a helix angle of between 30° and 45° and is a close fit within the operative end 12 of the tube.

A drive rod or cable 15 extends generally centrally through

the tube 11 and is supported at the operative end by a spider 16. The drive cable or rod 15 has a pair of location abutments 17, one on each side of the spider, to prevent the helical pump element 14 from moving longitudinally in the tube.

In use, the operative end portion 18 of the pump is placed in an area to be drained and the cable 15 or drive rod is rotated at a variable speed by a suitable motor 19. The motor can be for example a battery operated DC motor or a compressed air drive unit. Liquid pumped on the Archimedean screw principle through the flexible tube 11 is discharged through a discharge opening 20.

The helical pump element 14 is a close fit within the rigid operative end portion 12 of the operative end. The rotation of the helical pump element can provide variable speed pumping of liquid in either direction but, because there is always equality of air pressure at either side of the blades of the helix, since they are not hermetically sealed, gases are not pumped by the apparatus. In other words, if the pump is being used to drain liquid from an area, when the liquid has been exhausted, there is no tendency for large quantities of air to be drawn through the pump. Where the liquid is blood for example, this may reduce air entrainment and hence contamination and deterioration of the blood, which is particularly advantageous if the blood is to be recirculated to the body.

The grid or mesh 13 prevents large solids entering the tube, for example blood clots or portions of tissue.

Since there is no vacuum created, there is no suction effect on surrounding tissues. No air pump is needed to operate the device. The rate of fluid removal is more easily adjustable

than in a conventional evacuation unit.

Peristaltic or roller pumps are frequently used in pumping blood for surgical procedures. However; these are of heavy construction and act by compressing a tube externally, at the risk of crushing the cell structure of the blood being pumped. They have the advantage of being bidirectional.

- However using the pump described, bidirectional pumping at variable rates can readily be achieved without substantial damage to the blood cells and without extensive air entrainment.

Such arrangements may also be used for bedside, peritoneal dialysis systems or continuous ambulatory peritoneal dialysis systems.

Bidirectional pumps of the type described could be provided in a miniaturised version capable of insertion into an artery or vein to facilitate blood withdrawal or infusion in haemodialysis.

Although the applications described above are principally in the field of medicine and surgery, the pump may be applicable in many other contexts. It could be arranged to be operated from a conventional domestic electric drill.

CLAIMS

1. A pump comprising a tube which is at least partly flexible, one end of the tube being an operative end, a helical pump element sized to be close running fit within the tube, journal means rotatably mounting the helical pump element at said operative end of the tube, elongate drive means for the helical pump element disposed within the tube, and outlet means spaced from said operative end of the tube for outlet of liquid pumped thereby.
2. A pump according to claim one wherein the tube is flexible throughout its entire length.
3. A tube according to claim 1 wherein said operative end only of the tube is rigid.
4. A pump according to any preceding claim wherein the helix has an angle of between 30° and 45°.
5. A pump according to any preceding claim wherein the drive means comprise a flexible Bowden cable.
6. A pump according to any one of claims 1-4 wherein the drive means comprise a rotary drive rod.
7. A pump according to any preceding claim wherein said outlet means are laterally disposed at a position between the ends of the tube.
8. A pump according to any preceding claim wherein said operative end of the tube has a filter.
9. A pump according to any preceding claim and made of biologically acceptable synthetic plastics material.
10. A pump substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

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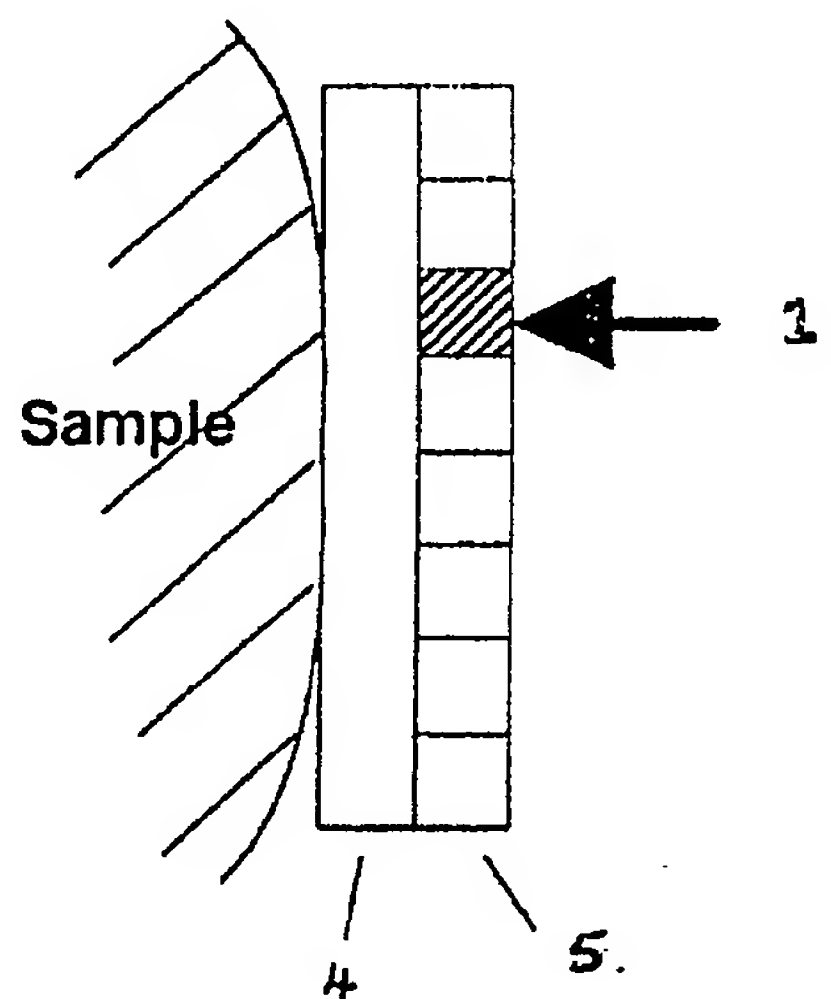
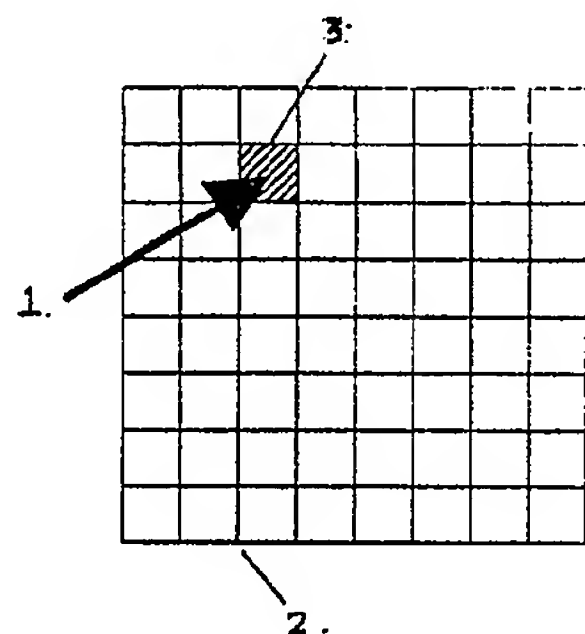
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(54) Optically controlled ultrasound array

(57) An optically controlled ultrasonic array comprises method and means of optically addressing and activating a slab of a suitable material which can be pixelated or continuous and which acts as a remotely controlled ultrasonic array. The slab is addressed and activated by a scanning optical beam or by an optical array, and replaces hard wired ultrasonic arrays reducing or eliminating transducer wiring and solid state switching. The scanned addressing and activation into acoustic oscillation of areas on the slab, effective pixel elements, is remote and faster than can be achieved by electronic switching of individual transducer elements on a conventional piezoelectric transducer array, eg. by optically switching electrical parts of the elements or by optically activating photo-sensitive cells which will generate the electrical signals necessary to energise the elements. The optical control can make use of a photo-thermal or photo-acoustic transduction process to generate acoustic waves. The system can be used for medical diagnosis or treatment as well as non-destructive testing or ultrasonic treatment, including plastic welding.

Diagram 4. Optically Controlled Ultrasound Array

Suggested embodiment:



At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1990.

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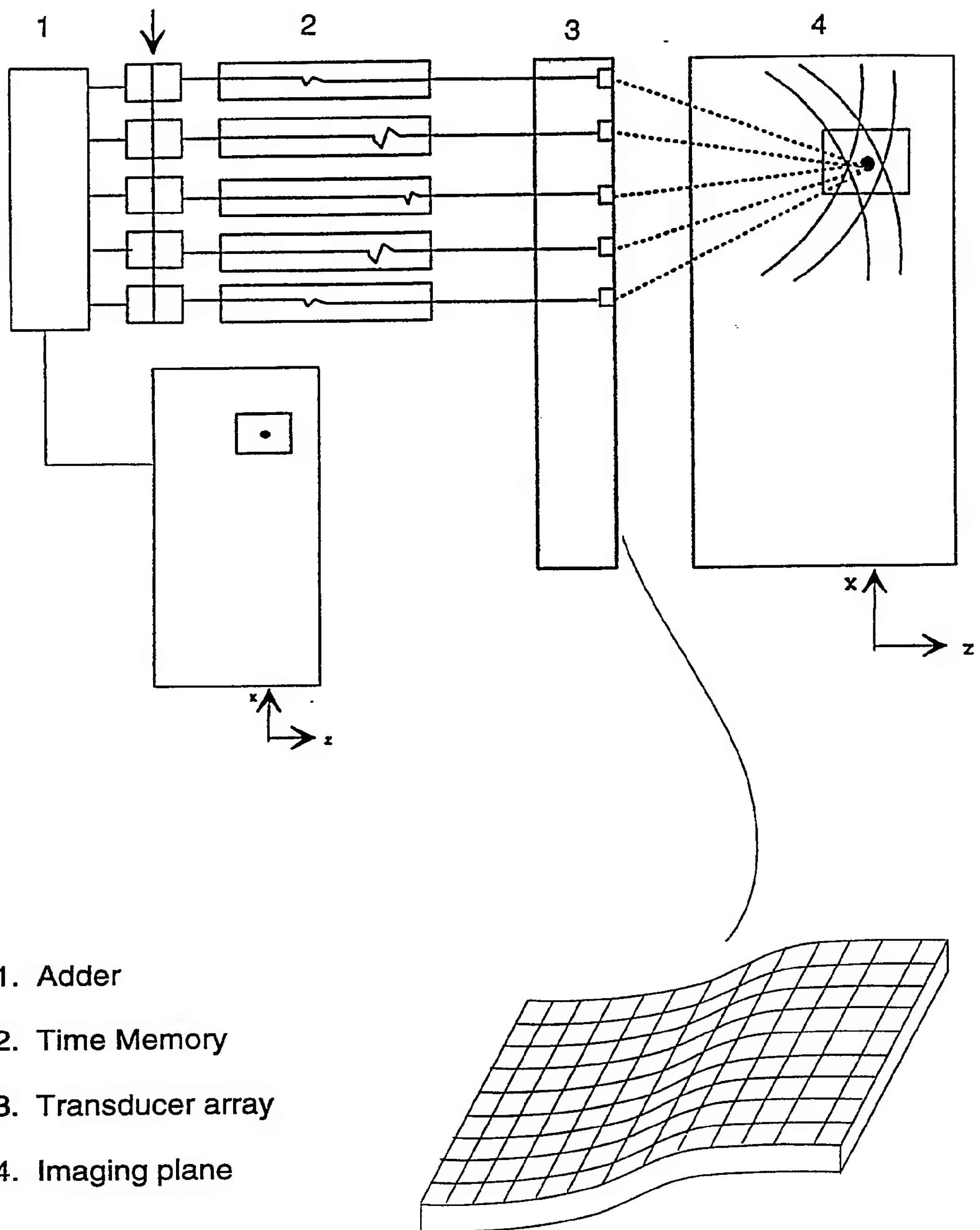


Diagram 1: Quasi-real-time synthetic aperture imaging (cf ref (4))

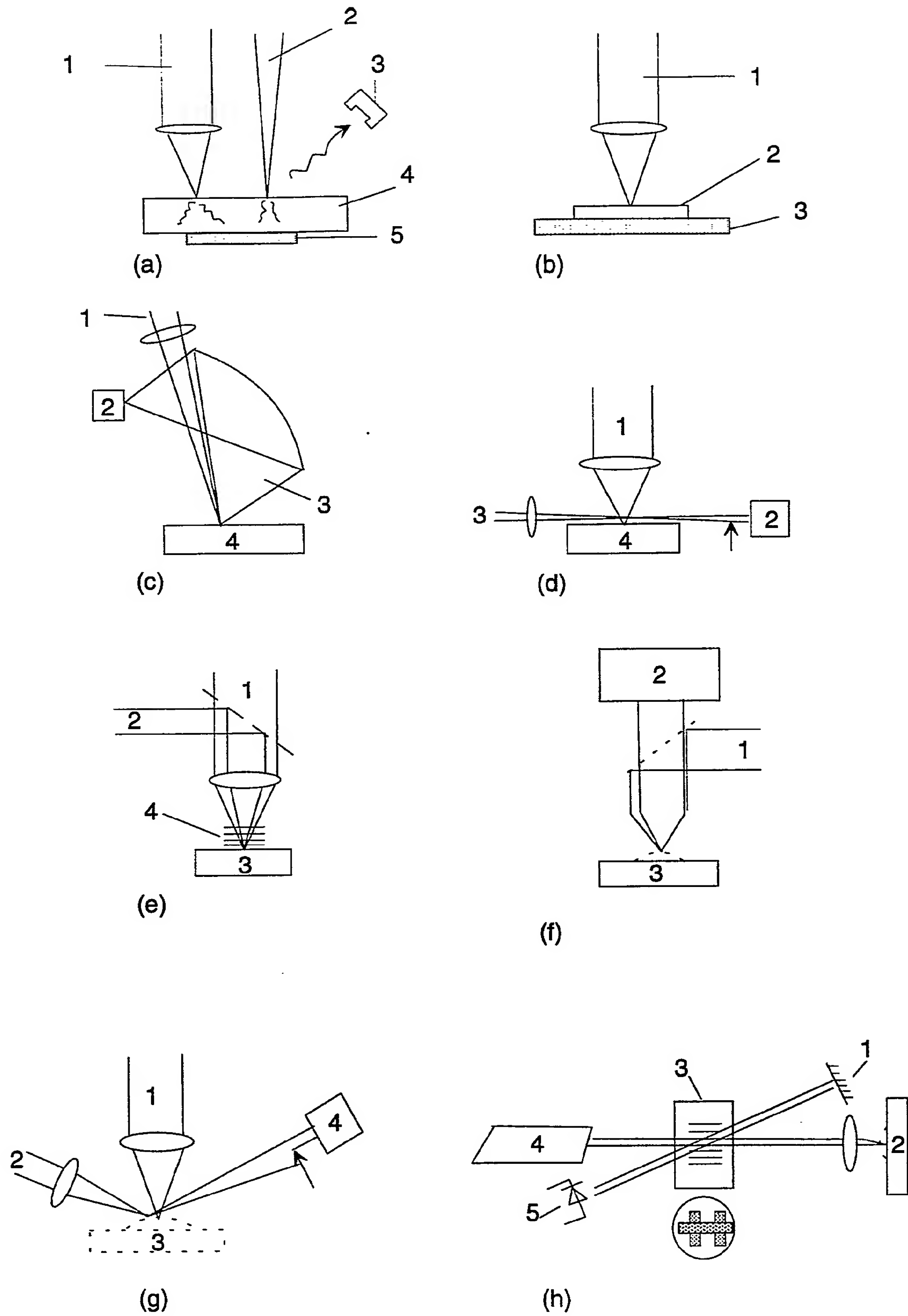
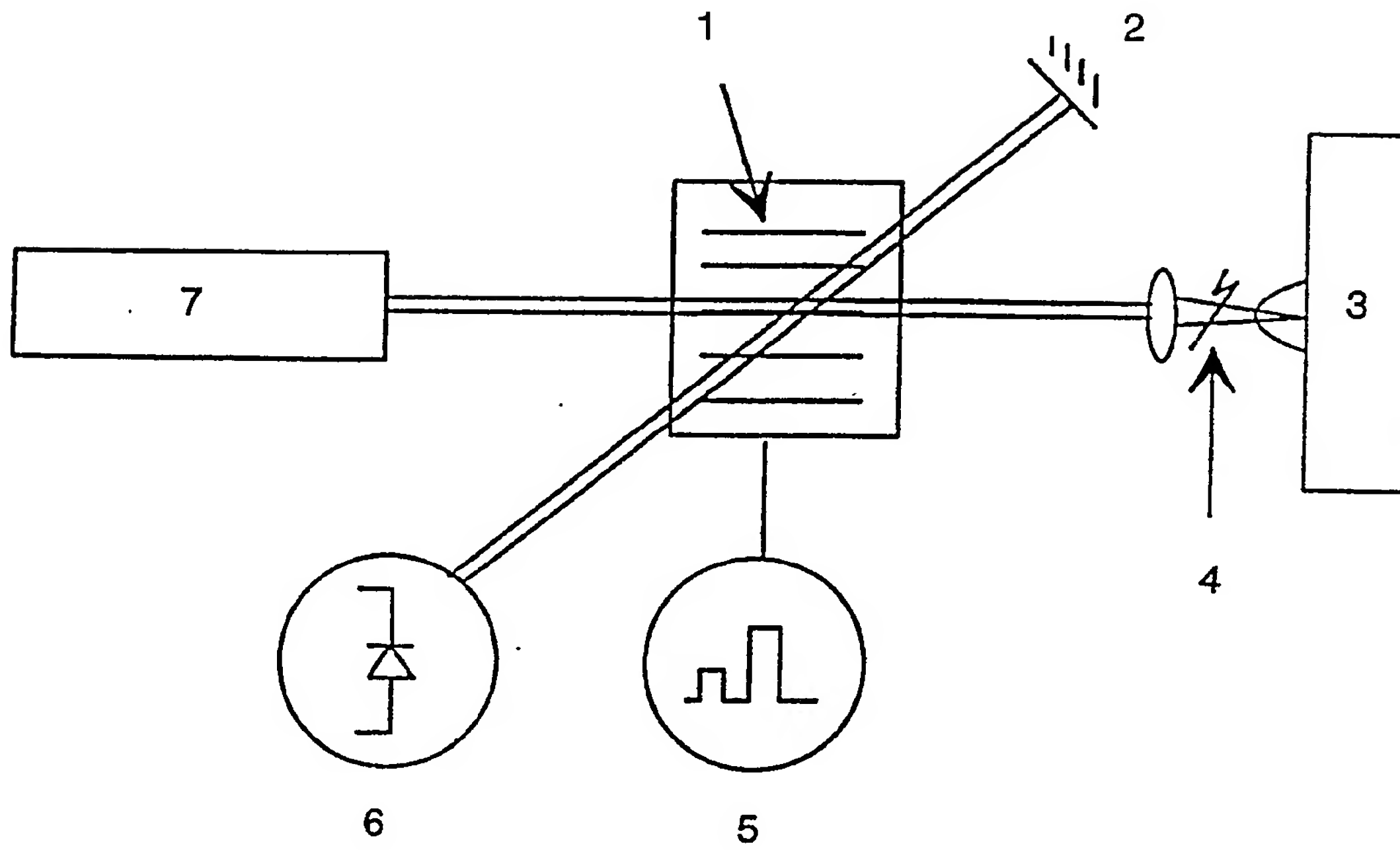


Diagram 2: Photo-thermal and photo-acoustic detection techniques



**Diagram 3: Photo-displacement sensing using laser probe
(modified Michelson interferometer)**

1. Adder
2. Time Memory
3. Transducer array
4. Imaging plane

Diagram 1: Quasi-real-time synthetic aperture imaging (cf ref (4))

(a) Photoacoustic

1. pump laser
2. electron beam
3. microphone
4. sample
5. PZT

(b) Pyroelectric Detection

1. pump laser
2. sample
3. pyroelectric detector

(c) Photothermal

1. pump
2. detector
3. thermal I.R.

(d) Mirage Effect

1. pump
2. detector
3. probe beam

(e) Bragg Scattering

1. pump
2. probe beam
3. sample
4. acoustic wave in the gas

(f) Photo-displacement
Interferometrical detection

1. pump
2. interferometer
3. sample

(g) Photo-displacement
detection by Beam Deflection

1. pump
2. probe beam
3. sample
4. detector

(h) Photo-Displacement with a single laser

1. mirror
2. sample
3. Bragg-cell
4. HeNe laser
5. photodetector

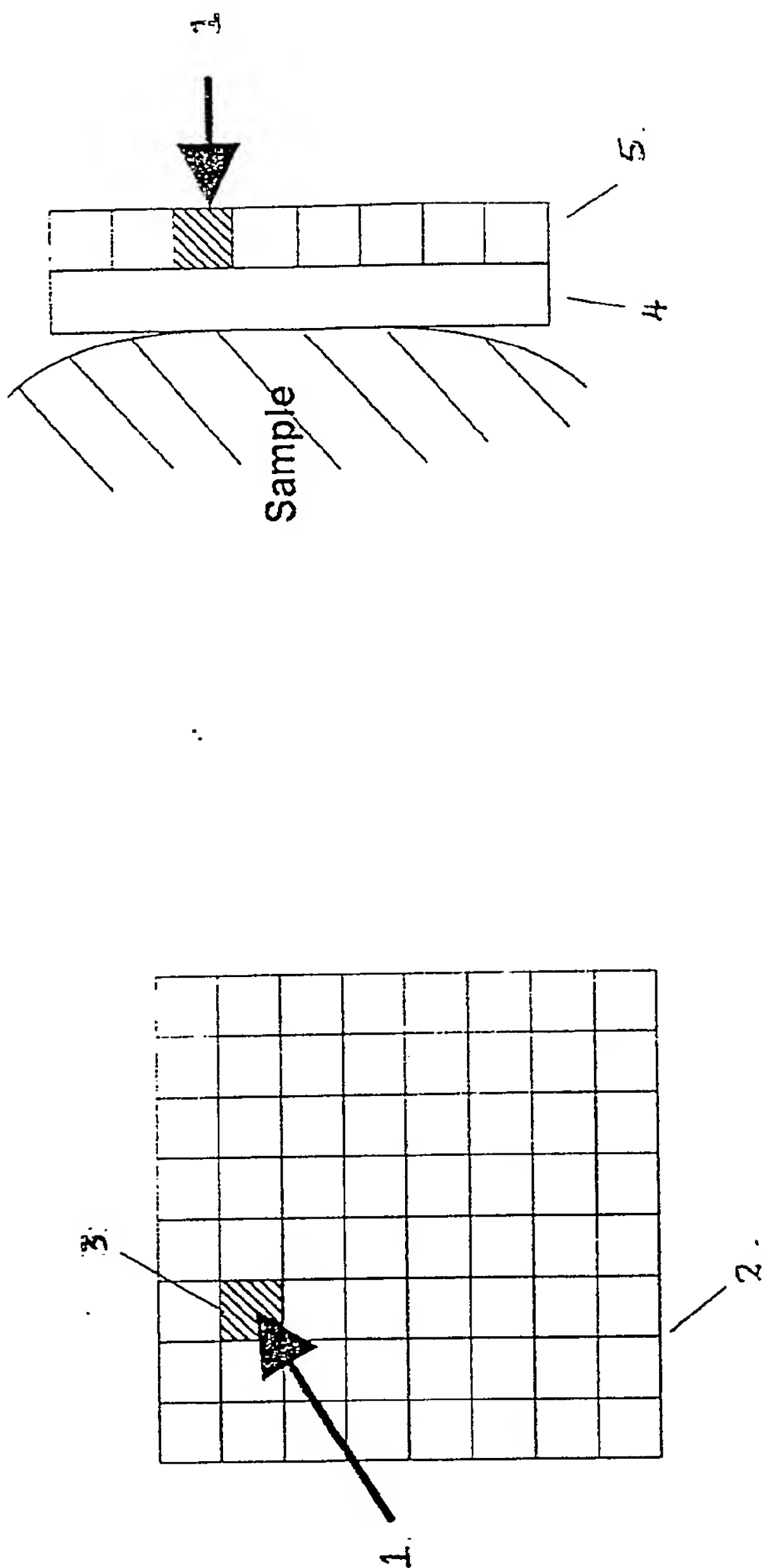
Diagram 2: Photo-thermal and photo-acoustic detection techniques

1. Bragg Cell
2. Mirror
3. Photoacoustic Transducer
4. Scanning Optics
5. Modulator
6. Detector
7. Laser

**Diagram 3: Photo-displacement sensing using laser probe
(modified Michelson interferometer)**

Diagram 4. Optically Controlled Ultrasound Array

Suggested embodiment:



OPTICALLY CONTROLLED ULTRASOUND ARRAY

Background to the invention

This invention relates to ultrasonic imaging or detection systems used in a number of applications including medical diagnostic imaging and NDT. These systems normally employ a transducer to change electrical energy into acoustic vibrations. These transducers are normally made of a piezoelectric material such as PZT, composite materials containing PZT or similar transduction material, PVDF, crystal quartz, LiNbO₃, ZnO each used depending on the frequency characteristics required. Transducers can also be made of magnetostrictive material.

The technology underpinning acoustic transducers is non-trivial and demanding applications in NDT and medical imaging constantly drive transducer technology improvements. Many of the imaging transducers are of a single element type which is then mechanically scanned. Applications for acoustic imaging range from a few KHz (sub-sea use) to several GHz (microscopy). One of the leading applications remains in medical imaging where frequencies in the few MHz range are used. Here, solid-state arrays are replacing mechanical scanners; single element transducers and annular arrays are being replaced by 1.5 and 2D arrays with dynamic focusing. Although, linear arrays with fine transducer pitch are in common use, the logistics of transducer manufacture and the considerable switching and processing has made a large, fine pitch 2D array as yet un-realistic.

The generation of acoustic waves through the interaction of light on a suitable material has many applications in imaging and defect detection, particularly in NDT. The phenomenon of Photo-acoustics was probably first used in practice by Alexander Graham Bell in 1880 ("On the production and reproduction of sound by light", Am. J. Sci., 20, pp 305-324). In 1881, Both Lord J.W. Strutt, 'Rayleigh' ("The photophone", Nature 23, p 274) and W.H. Preece ("On the conversion of radiant energy to sonorous vibrations", proc. Roy. Soc. 31, pp 506-520) provided some explanation of the phenomenon.

The generation of ultrasound by laser pulses was first suggested by 'Dick' R.M. White ("J. Appl. Phys. 34, p.3559) in 1963. A useful review appears in (D.A. Hutchins, Phys. Ac., Vol. XVIII, W.P. Mason & R.N. Thurston, eds., Academic Press, San Diego, 1988, pp.21-123).

In general, the generation of elastic waves using a laser, is accompanied by:

- plasma formation (metals)
- dielectric breakdown
- electrostriction and local piezoelectricity
- vaporisation, ablation or thermoplastic behaviour
- thermoelastic effects
 - photothermal
 - photoacoustic

The first four effects are related to high intensities. With lower intensities, one is in the thermoelastic effect, which is suitable for NDT and imaging. The interaction of light with matter is often accompanied by the coupling of energy

into an acoustic mode, in turn generating heat due to the thermal conductivity, viscosity and relaxation mechanisms in the material.

The periodic heating of the surface by a modulated light source gives rise to a temperature cycling. This can be detected thermally (IR radiometry, pyroelectric detection), optically (diffraction effects in the gaseous coupling medium in the vicinity of the heated spot) or acoustically (microphone on solid, gaseous photoacoustic cell). In general, the heating is accompanied by a thermo-elastic effect and a thermo-acoustic effect (heated gas). Photothermal and photoacoustic effects are thus both there and it is up to the detection scheme to use one or the other as an imaging mechanism.

The thermal diffusion length, the depth of effective penetration and interaction, is proportional to the root of the thermal conductivity and inversely proportional to the modulation frequency and the sound velocity. The thermal effect is governed by a diffusion process and it can be detected optically in the close vicinity (within one diffusion length) of the source, both in the imaging medium (skin) and in the coupling medium (air). Further afield, the acoustic effect can be detected using a suitable transducer (e.g. a microphone); in the air, the effect of the acoustic field is attenuated and also suffers a large impedance mismatch between the solid and the gas.

PRIOR ART

Ultrasonic array transducers are in wide use. At frequencies applicable to medical imaging, these are normally made of PZT, PZT/epoxy matrices or PVDF. In general, PZT transducers with only a few dB insertion loss ($20\log$ of the ratio between power in and power out) are possible, but bandwidths obtained are limited (5 to 20% typically). Using composites or PVDF, it is possible to obtain much wider bandwidths, even those approaching 100%, but inevitably, at the loss of efficiency (insertion losses of several tens of dB. PZT is a fired, compressed ceramic powder material, which is sturdy, but needs protection from moisture and extreme heat or large fields. Its acoustic impedance is c. 30MRayls, nearly two orders of magnitude higher than that of water. In order to improve the transmission of sound from the PZT element into water (or tissue, which has similar acoustic impedance) matching layers ($1/4$ wavelength thick) of soft materials such as silicon rubbers are used.

The technology of the transducer manufacture is thus non-trivial and demanding. For large arrays, the logistics of switching adds yet another level of extreme difficulty. Each transducer must be switched according to the phase or timing requirement of the array. The responses must be comparable from transducer to transducer. Each element must be able to cope with both large transmission signals and small return signals, at times 100 dB smaller than the transmitted signal. This requirement for large dynamic range imposes demanding specifications on the switching and amplification electronics; added to this are the speed requirements. First, there must be sufficiently fast recovery after the large transmission signals. Then, there must be sufficient on/off (extinction) ratios in the switches. Finally, there must be sufficient isolation from element to element.

The ultrasonic array transducer and switching assembly are then connected to the transmitter/receiver electronics through a cable, often with as many wires as there

are elements, sometimes with some of these having been coded and compressed so that the cable is not impossibly fat.

SUMMARY OF THE INVENTION

This invention provides an optical means of activating and addressing the ultrasonic transducer. In general, there are three ways in which one can achieve optical addressing and activation.

There are in essence three major aspects to this invention:

- Optically addressing and activating an ultrasonic transducer element by optically switching the electrical port of a conventional acoustic transducer element
- Optically activating a photo-sensitive cell which will generate the electrical signal necessary to energise a piezo-electric transducer
- Optically generating an acoustic signal by means of a photo-thermal/photo-acoustic transduction process through the absorption of the light energy. In this aspect of the invention, the acoustic wave can be generated either entirely by the light input, or by means of preconditioning the medium to need a limited light input to change its properties (eg matter phase change).

In all aspects of this invention, the optical addressing and activation will afford reduction or elimination of transducer wiring and solid-state multiplexing (switching); remote addressing; and fast scanning.

According to one aspect of the invention, acoustic waves are generated on the surface of a material to be tested (skin, metals, ceramics etc.) by an optical means of addressing pixel elements, which can be physically isolated or defined by the area of illumination. The pixel elements are designed to be light absorbing and generating an acoustic wave either directly or indirectly. In the direct method, the light absorbing pixel medium is designed for high photo-acoustic transduction efficiencies. In the indirect method, the light absorbing medium is designed for high efficiency photo-electric interaction.

DETAILED DESCRIPTION OF THE INVENTION

According to one aspect of this invention, the pixelated transducer is made of a series of adjacent cells filled with a light absorbing dye. In another aspect of the invention, the pixelated transducer is made of a simple single layer or a complex multi-layer sandwich of soft and solid material designed for optimum transduction efficiency. In yet another aspect of the invention, the slab is not physically pixelated, but pixel elements are in effect defined by the size of the laser spot scanning over the surface. The scanning laser light spot may be a single or a series of simultaneous spots allowing serial or partially parallel phasing

of the elemental sources.

The scanning of harmonically or amplitude modulated light over the pixelated slab causes a logarithmic increase and an exponential decrease in surface temperature, in harmony to the modulation of the exciting laser light. Depending on the thermal properties of the scanned surface, there may or may not be a nett increase in surface temperature, a dc effect superimposed on the ac signal.

One aspect of this invention relies on the photo-acoustic generation of thermo-elastic waves as the basis for a new type of ultrasonic transducer array with optical phasing. According to our invention, the ultrasonic array transducer consists of a slab of pixelated photoacoustic elements. An amplitude or harmonically modulated light source scans the surface of the pixelated slab, causing the generation of an ultrasonic wave within the light absorbing medium contained within the slab. This medium may be a light absorbing dye or a metal with good photo-acoustic properties.

The process of photo-acoustic transduction generally has very small quantum efficiency. It is nevertheless possible to generate sufficient acoustic signals as the generation and dissipation of sufficiently high optical powers as excitation is not a major difficulty.

The proposed system consists of:

- A high power semiconductor laser source (Generics is already capable of producing 25 W into an optical fibre);
- An intensity modulation system (mechanical or Bragg-cell based);
- A novel multi-element photo-acoustic transducer array as proposed by Generics;
- A detection mechanism (photo-displacement detection directly on transducer elements or separate single-element piezoelectric detector).
- A digital imaging algorithm and the associated hardware (e.g. the Stanford DAISY system)

The proposed transducer is intended to provide acoustic energy at ultrasound frequencies and is thus a possible alternative to medical ultrasound arrays in some applications. The principle of operation of the transducer is photo-acoustic because the ultrasonic energy is thermally generated.

Photo-acoustic imaging is an established technique in NDT and much work has been carried out describing resolution and contrast mechanisms in microscopic imaging applications [6-10]. The art will be familiar to experts.

Thermal waves can be generated by any time-varying heat source. Light absorbed locally and characteristically by the illuminated portion of a sample is converted partly into thermal energy due to absorption. In harmony with the incident light intensity modulation frequency, a periodic heat flow results into the surrounding

region. This periodic heat flow (diffusion) is non-radiative within the sample because it is so highly damped that it reduces to $1/e$ of its peak within one wavelength (the thermal diffusion length). The periodic heat flow also results in an acoustic wave which is not critically damped and thus propagates like a normal wave, interacting with and attenuated by sample properties over a much larger distance. In general, three processes contribute to the contrast:

- Local variation in the light energy absorption characteristics of the surface (reflection, absorption, de-excitation)
- Scattering of photo-acoustically generated thermal waves
- Scattering of photo-acoustically generated ultrasonic waves

High resolution photo-acoustic microscopy has depended mainly on the first of these effects, thus providing surface contrast. Interior imaging microscopy (ie photo-thermal microscopy) has depended largely on the second. The proposed medical ultrasound array will be based mainly on the third.

Typically, modulation frequencies in the 100 kHz to 10 MHz or more result in thermal wavelengths in metals of $10 - 1 \mu\text{m}$ (some five times less in thermal insulators). However, the corresponding acoustic wavelengths are in the order of $15 \text{ mm} - 150 \mu\text{m}$. In photo-acoustic and photo-thermal imaging using low chopping frequencies, the acoustic wavelength is too coarse to be of interest and as a result, the acoustic wave is used as a carrier for finer thermal information. The Generics concept however makes use of the propagating acoustic wave in its interaction with the sample. In the case of medical imaging, it is intended typically to work at 2 to 5 MHz for useful resolutions.

The Generics concept thus boils down to using the photo-acoustic effect as a source of scannable acoustic energy in a new type of medical ultrasonic array.

FOCUSING AND SCANNING

Although it is appreciated that an ideal solution to fast imaging applications such as blood flow and certain specific cardiac cases is very important, we consider this to be a specialised area of flow analysis as opposed to imaging. It is, in our opinion, premature to address this particularly demanding specific case. During the discussion, we postulated 3D imaging and thus mainly spoke of a 2D array. It is indeed the expectation that the Generics concept will address 3D imaging applications; the approach will be to design first a linear array, followed by a phased array [1,2,11,12,13]. We thus describe the operation principle of a linear array as a basis of operation for a 2D array (3D imaging).

In a linear array, a single or a group of elements are fired to illuminate the sample in a direction normal to the face of the array. The scanning is performed by translating across the face of the array the firing sequence. In a phased array, a larger group of more closely packed transducers are fired simultaneously with appropriate phase (or timing) in order to produce a steerable focus.

There are a number of possible modes in which the proposed transducer may be scanned and a focus produced. We have postulated a system, which, on the

limit, relies on sequential triggering of a single transducer at a time. This will be the worse (slowest) case. We thus choose this case as an example to illustrate how the focusing and scanning may be achieved. Furthermore, the description is centred on a linear transducer capable of producing a B-scan image. Other more complex modalities are possible, but their working principle will be essentially based on the simpler steps to be described here.

In an ideal transducer both efficiency and bandwidth are high. The photo-acoustic transduction process is a lossy process and it is expected that efficiencies will be low and bandwidths fairly high. Efficiency will allow detectable return signals with sufficient dynamic range. Bandwidth will allow short pulse operation and thus both high inherent depth resolutions and faster possible scanning/processing rates.

We propose, as a possible limiting case, a system using synthetic focusing of acoustic images. Such a system has been proposed and successfully demonstrated and implemented elsewhere, on a switched, hardwired, conventional acoustic transducer array [3,4]. The adaptation of the system to the proposed photo-acoustic system is best explained on diagram 1.

In transmit mode, the Bragg cell modulates the intensity of the laser beam at the required frequency, say 2 MHz. The modulated beam is then made to scan over the surface of the array (initially a linear array) so as to excite, with a pulse, a single element at a time (it may be possible to illuminate several elements simultaneously for phased array mode). Assuming a 30% bandwidth, the shortest possible pulse will be 1500 ns. Assuming an attenuation of 2 dB/cm in tissue, an imaging depth in B-scan mode of 5 cm will result in two-way attenuation of 20 dB at normal incidence. The wavelength in the tissue will be in the order of 750 μ m and in the transducer possibly in the order of 1.5 mm. A transducer pixel of this proportion will have a Fresnel distance of approximately 200 μ m at which little self-focusing occurs. The 3 cycle pulse emanating from the transducer will then travel into the depth, with any echo from 5 cm depth returning between 66 microseconds (at normal incidence) and c. 100 microseconds (for a 32 element array of say 8 cm length). If an image area of say 256x256 is required, the return signal can be quantised in .4 microsecond intervals, corresponding to a fraction of the 3 cycle pulse, well over the Nyquist limit. Allowing up to 100 microseconds delay per element, sequential triggering will translate to a frame rate of c. 3 ms or 300 Hz. With a 20 MHz clock rate, 10 samples per wavelength would be possible and up to 300 frames can be produced every second.

In receive mode, for every point of interest in the xz B-scan plane, a look-up delay table will give the appropriate pre-calculated delays per element channel. For each channel, a feature in time could have emanated from any point on a circle centred at the element and within the imaging area. By adding the time corrected signals from all the elements, as in a backprojection, the intersection between these circles, corresponding to the position of the feature is emphasised by the sum of the intensities. The received signal is upshifted by twice the modulation frequency as it passes through the Bragg cell for a second time before detection.

In a 2D array of say 32x32, one simple way of producing 3D images would be

to repeat the above operation for all elements, resulting in complete coverage of a volume approximately 8x8x5 cm in approximately 100 ms.

It is thus conceivable that real-time imaging will be possible even in 3D mode. At these rates, a jitter of 10 m/s from a feature in the tissue will cause an error of one two hundredth of a wavelength in the depth direction and around one wavelength from adjacent elements in the lateral direction.

We conclude that a quasi-real-time imaging system based on sequential aperture synthesis is likely to be possible. There is thus no need for the array to be either simultaneously illuminated nor for it to be illuminated necessarily within the phase delay between the closest and the farthest elements to points of interest in the imaging area.

DETECTION PRINCIPLE

Whilst a number of detection schemes may be proposed (single piece piezoelectric detector, charge coupled delay devices etc.), it is likely that the signal levels will be too low for most of these. Signal levels are briefly discussed in the next section.

We consider first, detection based on a single piezoelectric element of wavelength proportions placed in the centre of the photo-acoustic array. It is shown in the next section that acoustic power levels c. 1mW can be expected for laser power input of 25 W, after a number of simplifying assumptions. In such a case the signal will be easily detectable and the detection bandwidth will not be a limiting factor. The implications of this on the scanning logistics must be considered. In transmit mode, the scanning is as described previously. In receive, however, the x,z position of the raster scan will correspond to a single distance, from the fired transducer to the x,z point and back to the receive transducer. This distance is unique for every fired transducer. Looking at the reflections due back from each fired transducer, the stored value for each delay could map to a number of possible positions. The aliasing thus produced is gradually corrected as the response due from other transducers are also added, emphasising true reflection features in common amongst the various transducers. This problem will be reduced if a phased array is employed, as the point of focus will be predefined during transmission.

The implications of the above during transmission scanning is that each line should be scanned fast enough for the longest delayed and shortest delayed returns to interact. For a 38 degree aperture half-angle (F 1.6) array to focus at one corner 5 cm deep, the shortest time is 66 microsecond and the longest 126 microsecond allowing 60 microsecond for scanning the elements sequentially, 17 kHz line rate (1.87 microsecond per element on a 32 element array). To focus at 1 cm depth along the axis of the transducer, this time difference is reduced to 14 microseconds. Thus the scanning speed and direction will define the focus uniquely in transmit. The digitised returns can be limited to a specific time window, expected to be the delay between the defined focus and the receive transducer. Thus during reconstruction, each x,z point in the raster will be associated to a specific memory location where the digitised return signal has been stored.

Naturally, it would be attractive to uphold the wireless nature of the transducer in receive mode also and to this end, we consider an alternative detection scheme using optical detection.

A number of photo-thermal and photo-acoustic schemes have been proposed in the literature and shown schematically in diagram 2, amongst which we propose a very highly sensitive surface displacement detection scheme known as photo-displacement microscopy [5], shown separately in diagram 3. This scheme is fairly well established and is otherwise known as the laser probe technique and has been demonstrated to produce sensitivities to 10^{-4} angstrom displacements per Hz bandwidth.

To this end, a modified Michelson interferometer is used which incorporates an acoustically controlled Bragg cell. The Bragg cell will act as an active grating/splitter performing a number of tasks, amongst which are:

- Beam scanning;
- Intensity modulation of the incident beam;
- Isolation of incident and received beams in the frequency domain;
- Heterodyning of the signals for detection;
- The use of a single laser for surface heating and for displacement detection.

The photo-displacement signal is shifted to the second harmonic of the Bragg modulation frequency and easily detected in a bandwidth appropriate to the signal to noise levels achieved. It is this final detection bandwidth which is believed will ultimately define the frame rate.

Two possible modes of detection were described. It is concluded that although the detection scheme will be non-trivial, it will nevertheless be possible either to detect the signal using a piezoelectric element in the centre of the photo-acoustic array or to employ a photo-displacement sensing technique based on a modified Michelson interferometer capable of 10^{-4} Angstrom/Hz depth resolution.

SIGNAL LEVELS

A full analysis of overall signal to noise performance of the system will be required. We present here some preliminary considerations.

We assume a 25 W laser power over an area of 400 dimensions (This is a power density presently achieved by Generics designed semiconductor laser cluster).

Using one-dimensional theory, the peak temperature rise can be shown to be proportional to the peak laser power density and inversely proportional to the chopping frequency, density, specific heat capacity and the thermal diffusion length. For the 25 W laser power into fibre dimensions, this translates to a temperature rise of c. 13 degrees in water (.2 in a metal) per cycle. This corresponds to a deflection in the order of 10^{-7} m on the surface of the heated

spot. Based on further assumptions yet to be verified, we calculate strains of 10^{-4} , translating to an acoustic power output in the order of one Watt. Upon return from say 5 cm within tissue, this power will be reduced by some 30 dB, resulting in an acoustic power of 1 mW, c. 0 dBm, which is easily detectable acoustically from a single transducer.

These calculations and the assumptions taken are for illustrative purposes only and it is not suggested that a full 25 W laser will be used, nor that signal levels detected will be purely based on the above assumptions.

Based on the assumptions taken, it is concluded that adequate signal levels may be produced.

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- Diagram 1. Quasi-real-time sequential synthetic aperture imaging (cf ref. [4])
- Diagram 2. Photo-thermal and photo-acoustic detection techniques
- Diagram 3. Photo-displacement sensing using laser probe (modified Michelson interferometer)
- Diagram 4. Optically controlled ultrasound array

Optically Controlled Ultrasound Array

Claims

- 1 An ultrasonic or acoustic transducer element or array which is addressed and activated by optical means.
- 2 An ultrasonic or acoustic transducer element or array which is addressed and/or activated remotely.
- 3 A wireless ultrasonic or acoustic element or array.
- 4 A method of remotely generating or controlling acoustic or ultrasonic signals for the purpose of medical diagnosis or treatment or industrial non-destructive testing or acoustic treatment such as welding.
- 5 A means of generating acoustic or ultrasonic signals remotely by using a slab of pixelated or continuous material that is addressed by a scanning optical beam or an optical array.
- 6 The element or array of claim 1 where the electrical port of a conventional acoustic transducer element is optically switched.
- 7 The element or array of claim 1 where the optical addressing energises a piezo-electric transducer element or array through use of photo-sensitive cells.
- 8 The element or array of claim 1 where the acoustic signal is generated through a photo-thermal or photo-acoustic transduction process.
- 9 An acoustic or ultrasonic transducer element or array, where the scanning of the array is achieved through optically addressing the surface of the array directly, the surface being pixelated or continuous.

-13-

Patents Act 1977
Examiner's report to the Comptroller under
Section 17 (The Search Report)

Application number

GB 9205577.1

Relevant Technical fields

(i) UK Cl (Edition L) G1G (GED, GEEA, GET, GES);
H4J (JCX)

(ii) Int Cl (Edition 5) G01N (29/24); G10K (15/04);
H04R (17/00, 23/00)

Search Examiner

D L SUMMERHAYES

Databases (see over)

(i) UK Patent Office

(ii) ONLINE DATABASE: WPI

Date of Search

8 JULY 1993

Documents considered relevant following a search in respect of claims 1-9

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	GB 1583057 (IBM)	1-4
X	US 4512197 (GUTFELD)	1-5, 9
X	US 4469977 (QUINN)	1-4
X	US 4269067 (TYNAN)	1-4
X	IBM Technical Disclosure Bulletin, Vol 21, Number 8, January 1979, R J von Gutfeld and S S Wang, "Laser Generated Acoustic Fan Beam Ultrasound TOMograph System" pages 3441-3442	1-4

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family, corresponding document.

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).

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(51) INT CL⁷

A61N 5/06

(52) UK CL (Edition S)

A5R REHR

(56) Documents Cited

EP 0266038 A WO 99/19024 A WO 98/43704 A
WO 01/14012 A WO 00/15296 A US 5616140 A

(58) Field of Search

UK CL (Edition S) **A5R REHR**
INT CL⁷ **A61N 5/06**

ONLINE: EPODOC, WPI, JAPIO

(54) Abstract Title

Therapeutic light source and method

(57) A therapeutic light source, for example for photodynamic therapy (PDT), comprises comprising an array of preferably independently switchable red and blue light-emitting diodes L_R , L_B , mounted on a flexible backing.

Other arrangements of non-planar arrays of LEDs are also claimed, both for external and internal use as well as light sources comprising LEDs having specific emission wavelengths.

FIG. 26

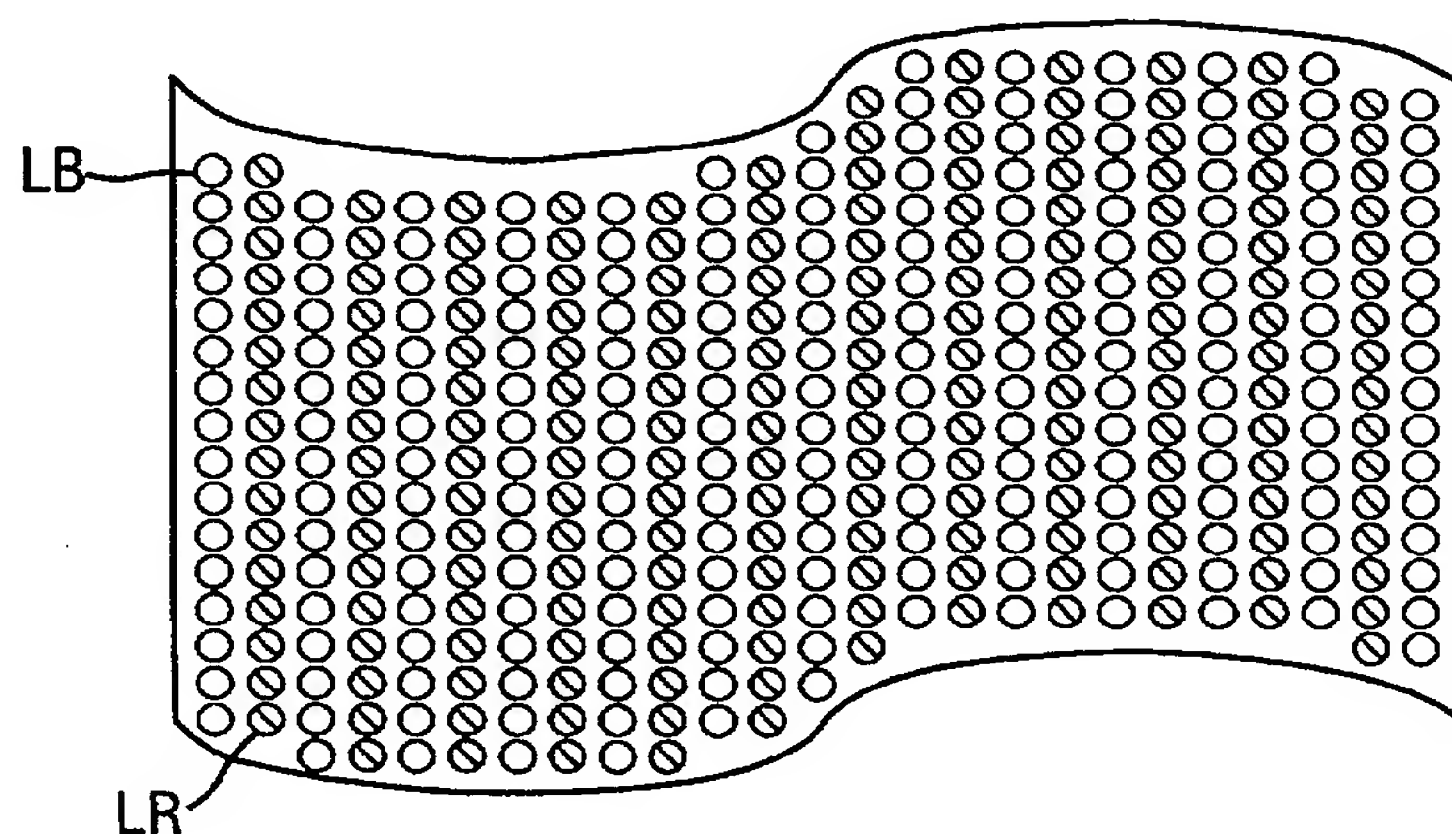


FIG. 1

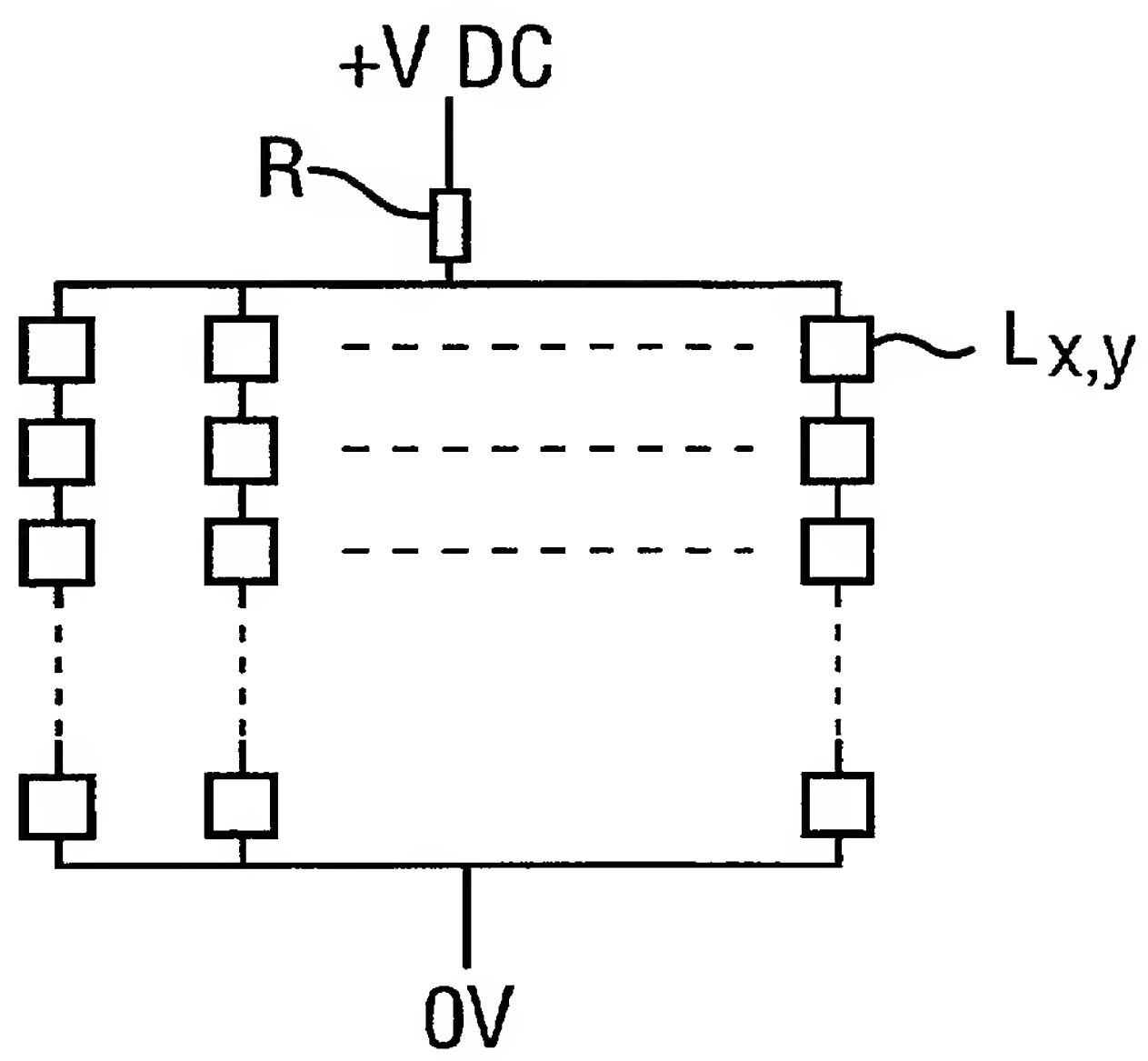


FIG. 5

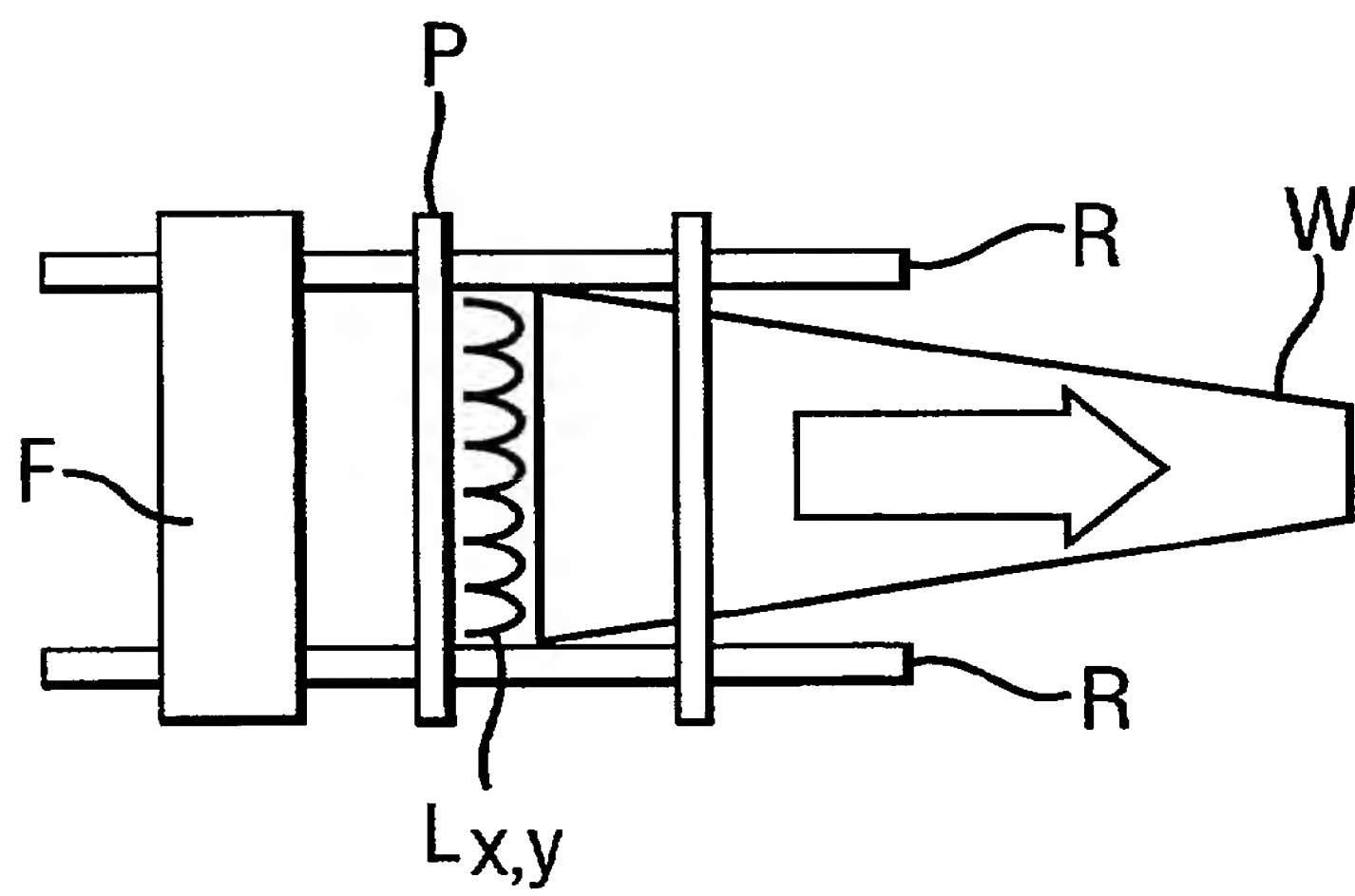


FIG. 2

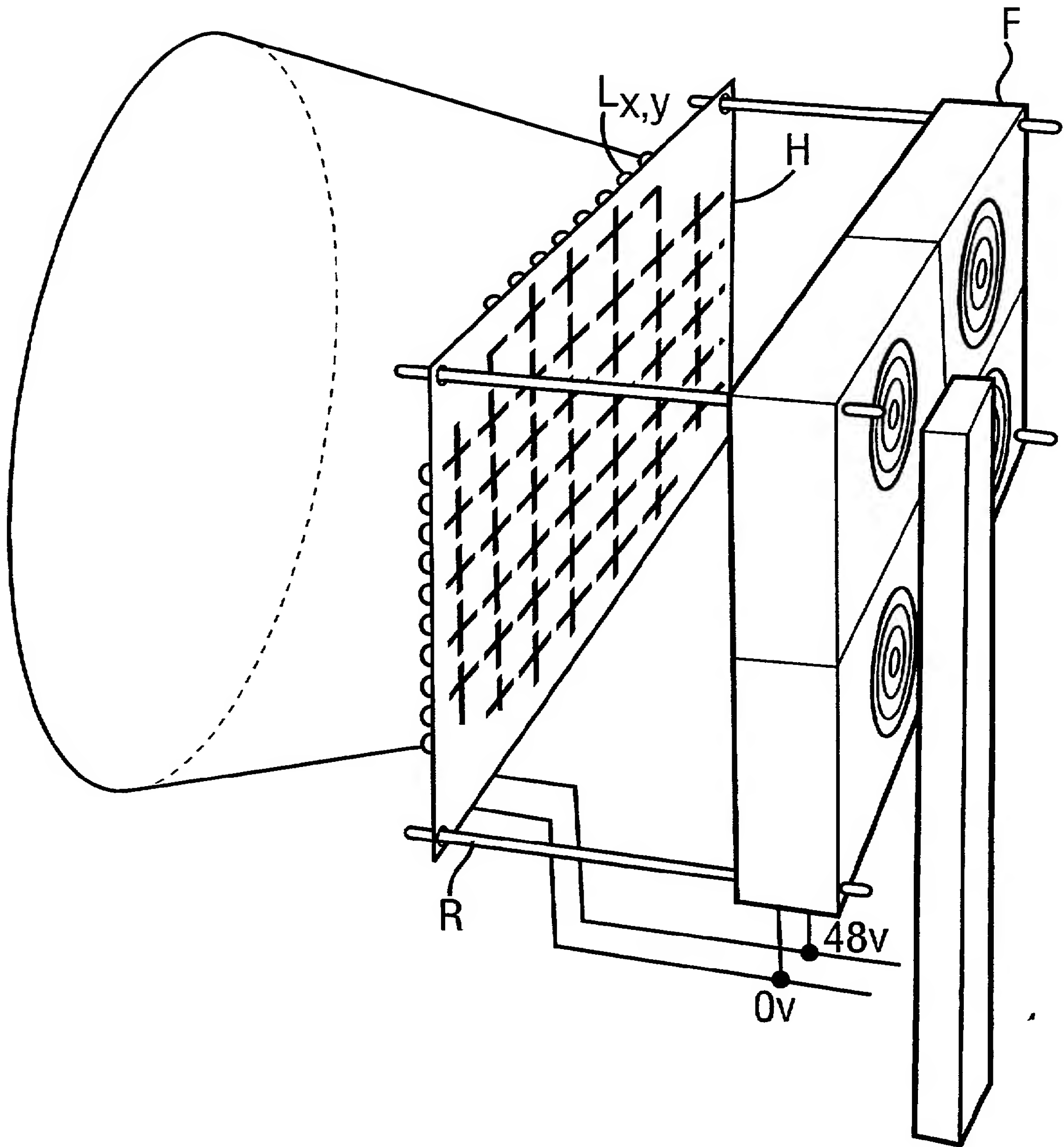


FIG. 3

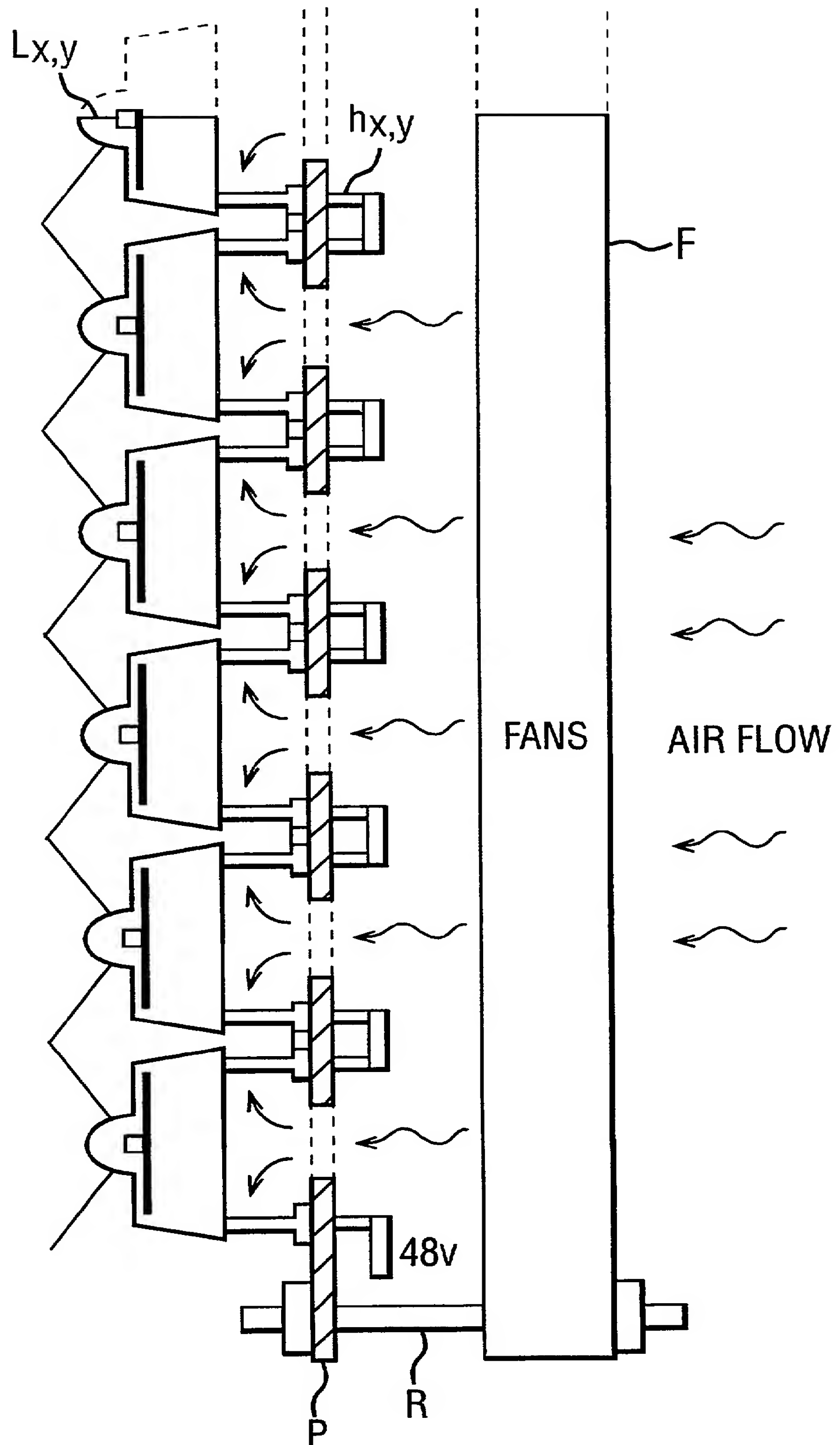


FIG. 4

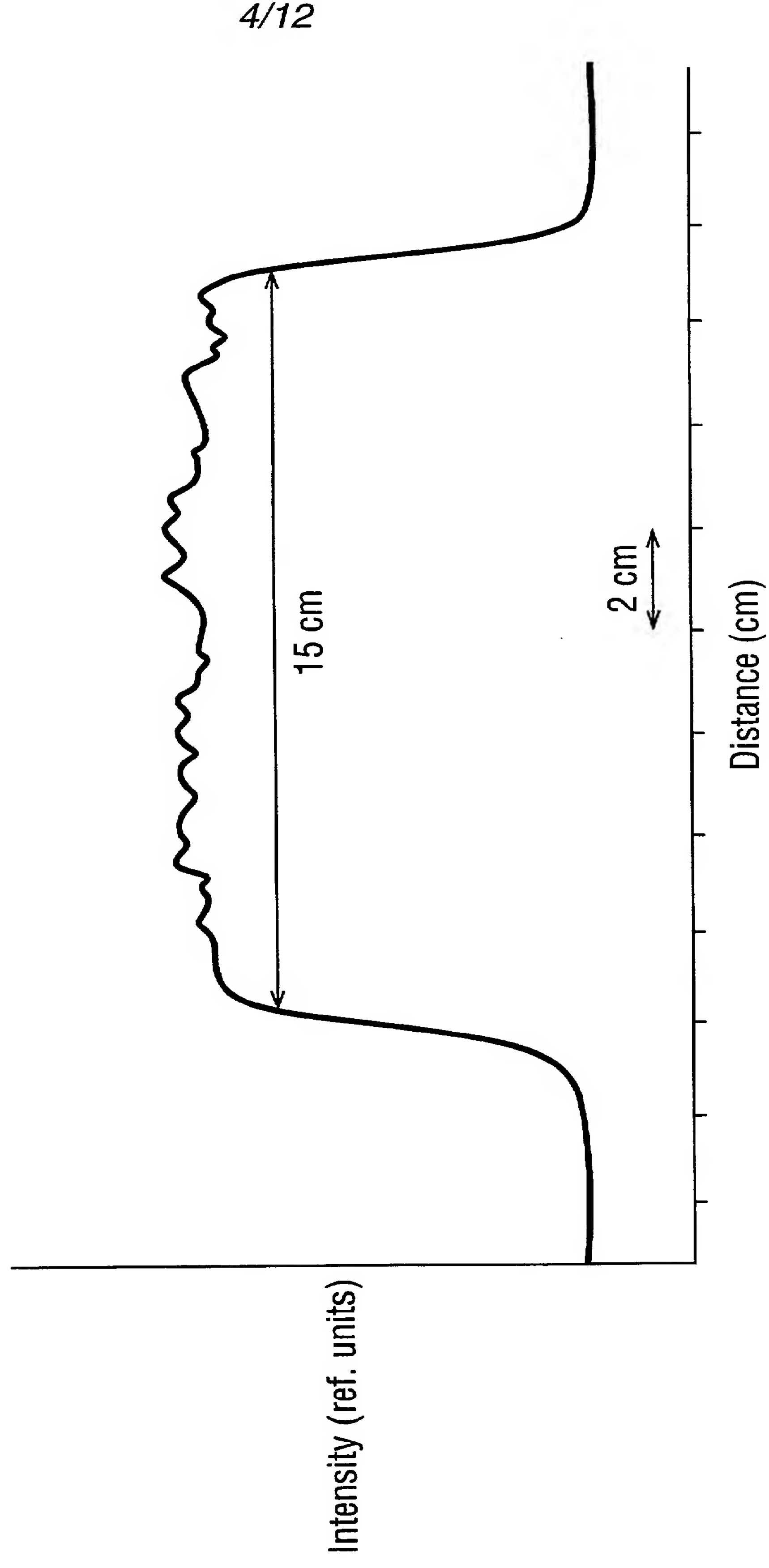


FIG. 6

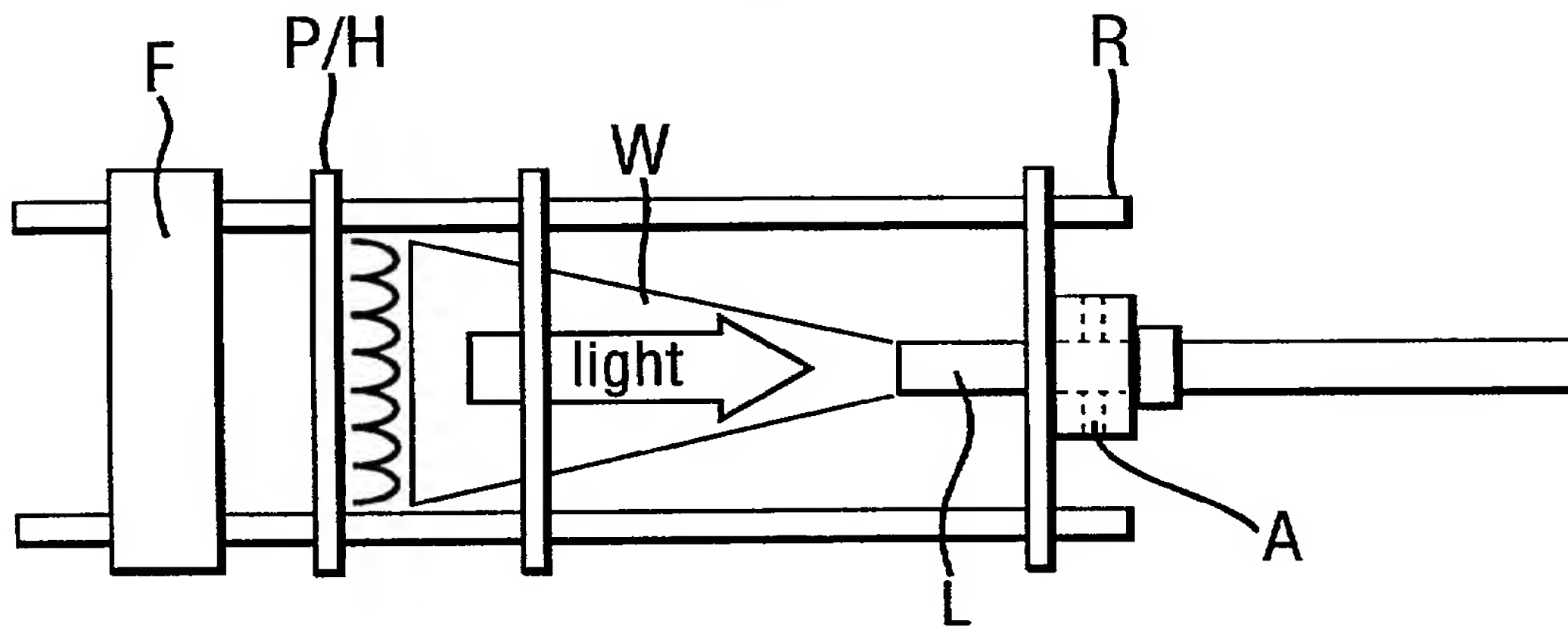


FIG. 7

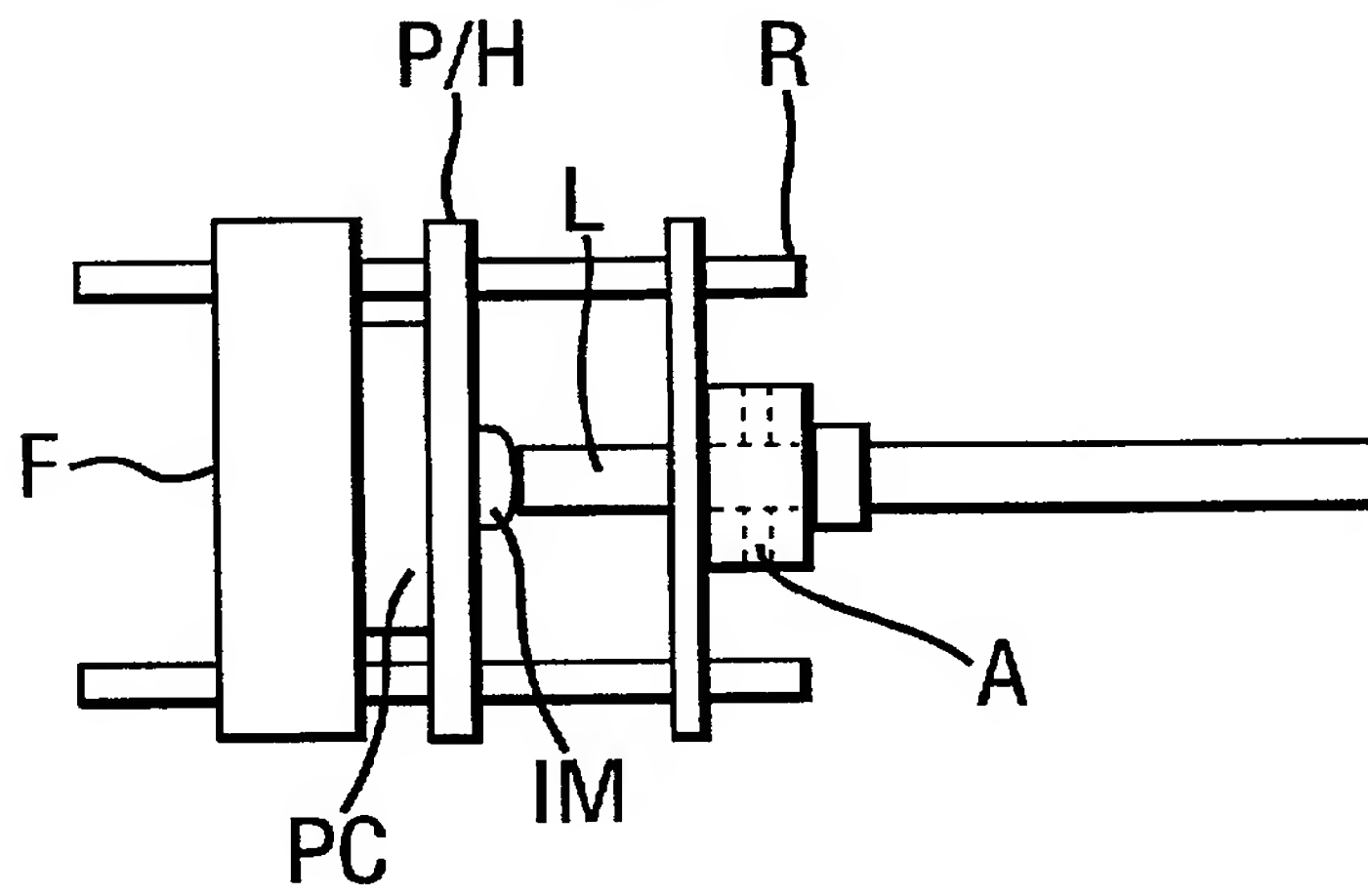


FIG. 8

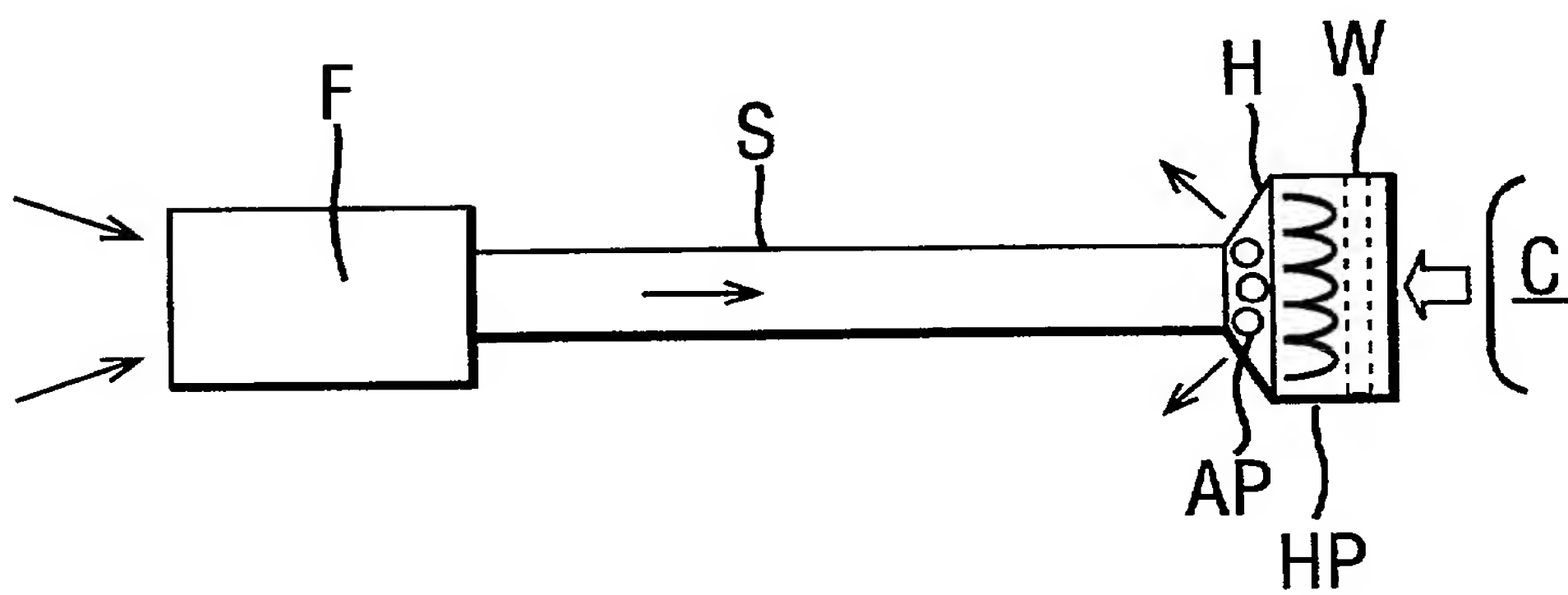


FIG. 9

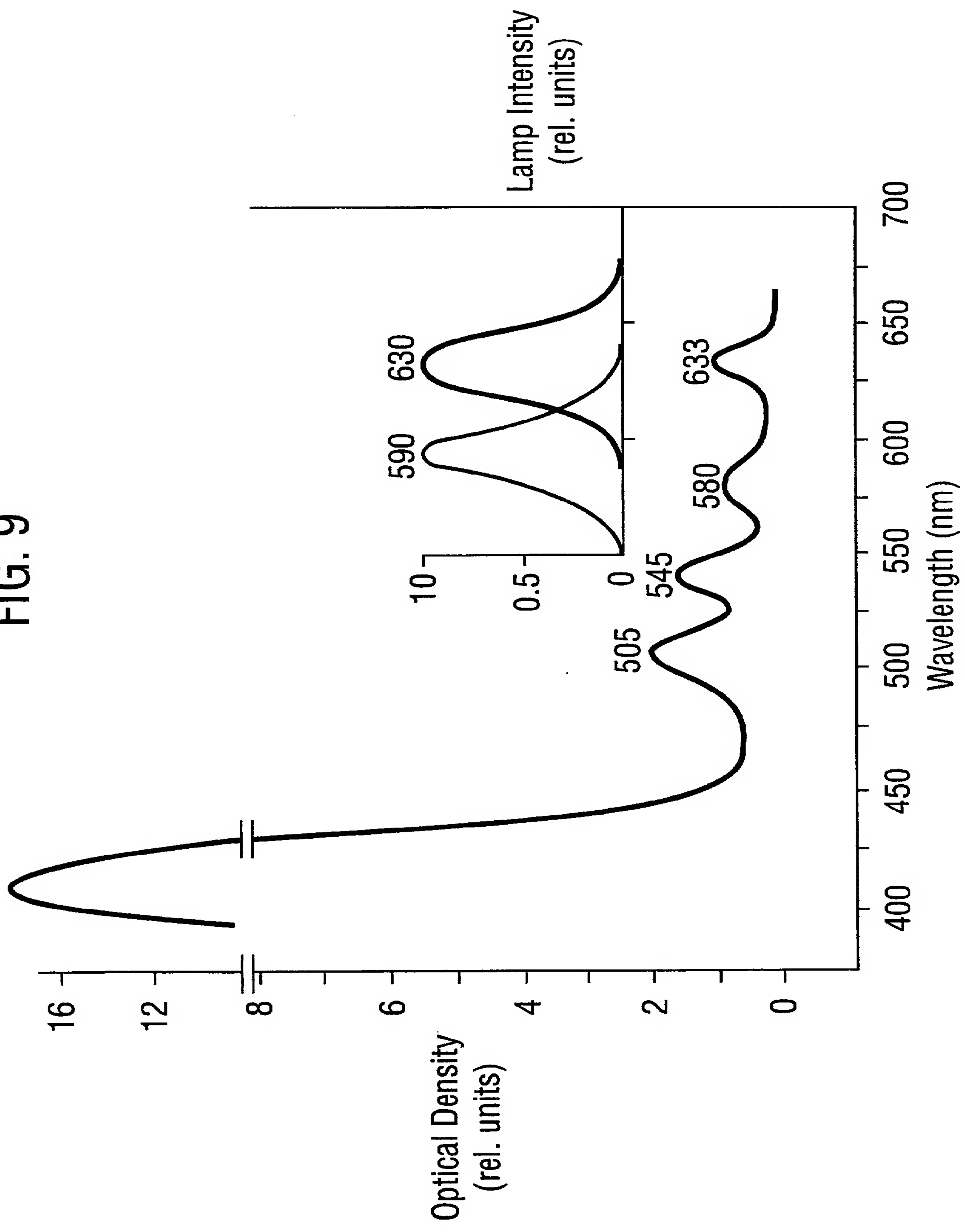


FIG. 10a

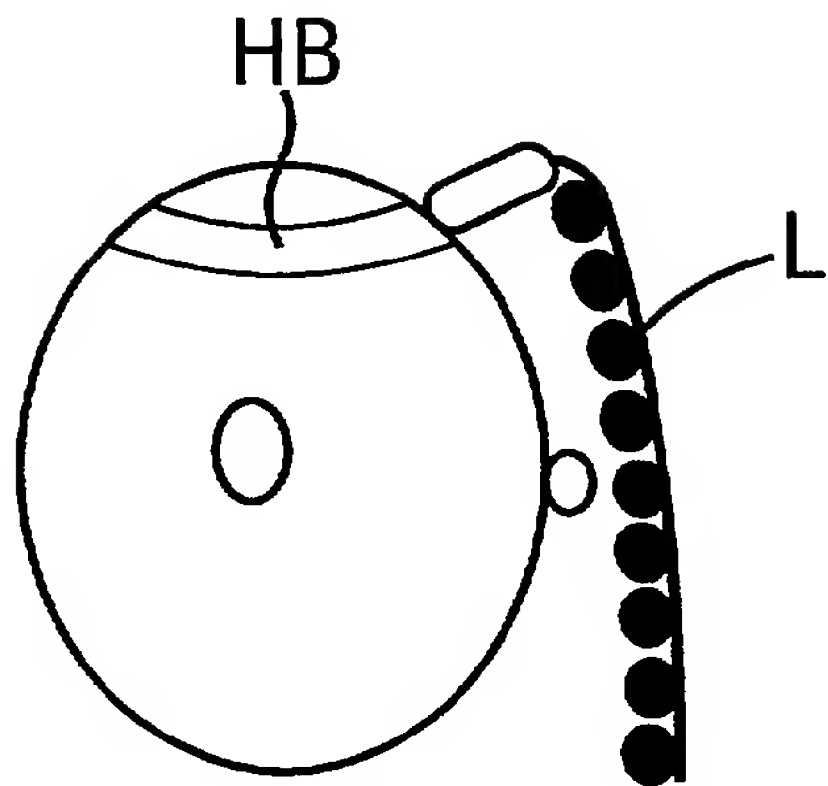


FIG. 10b

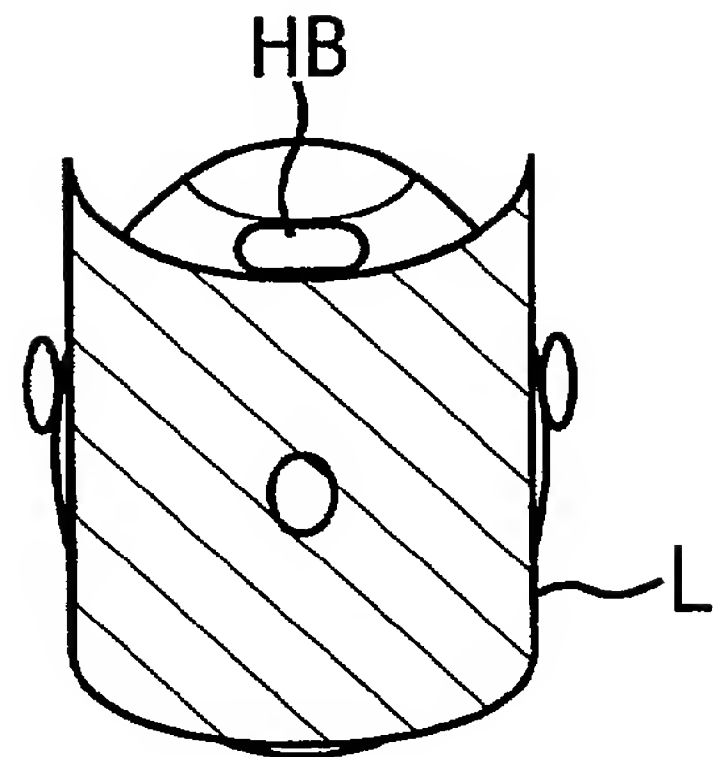


FIG. 11a

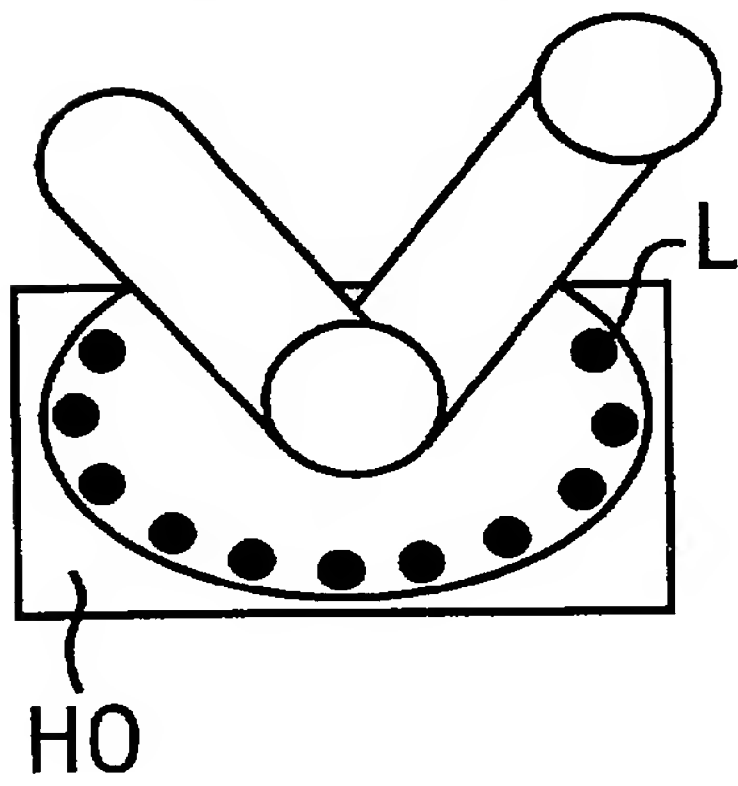


FIG. 11b

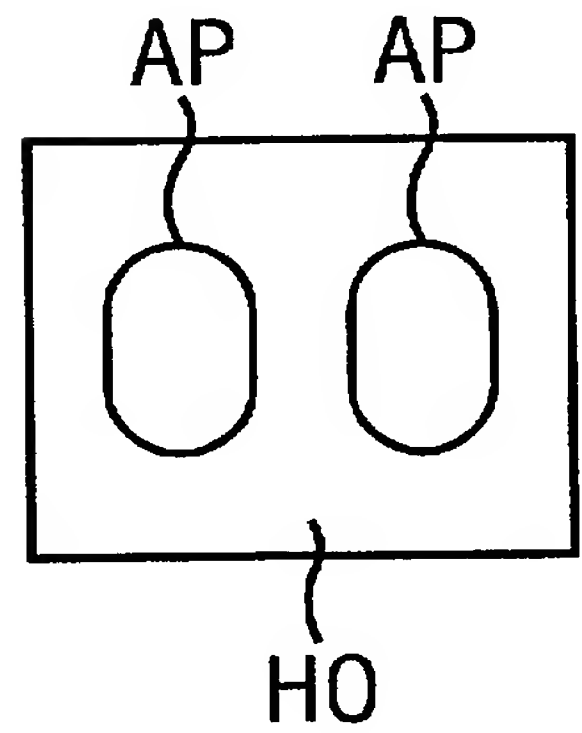


FIG. 11c

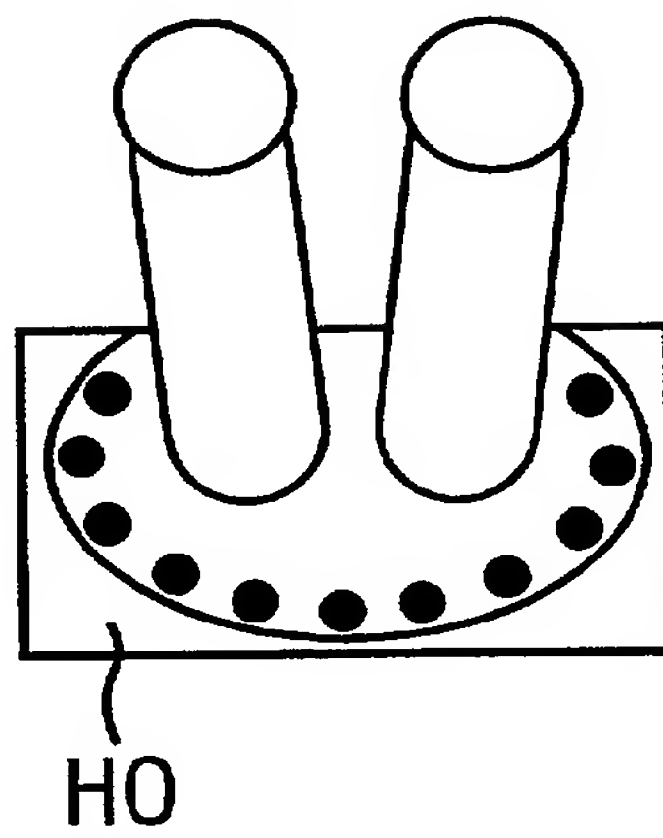


FIG. 12

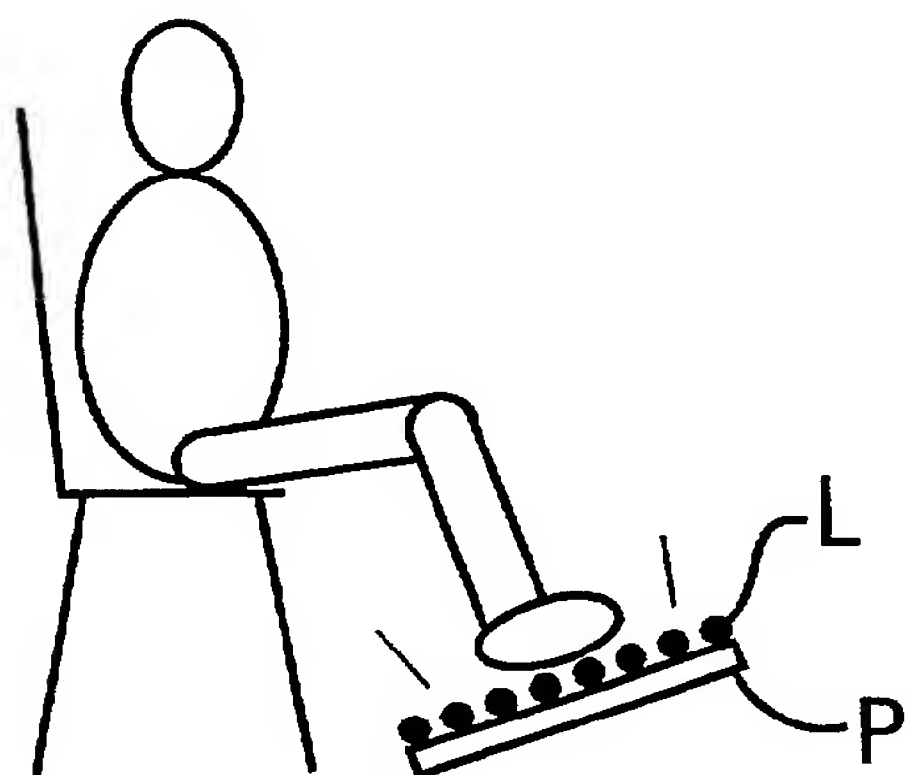


FIG. 13

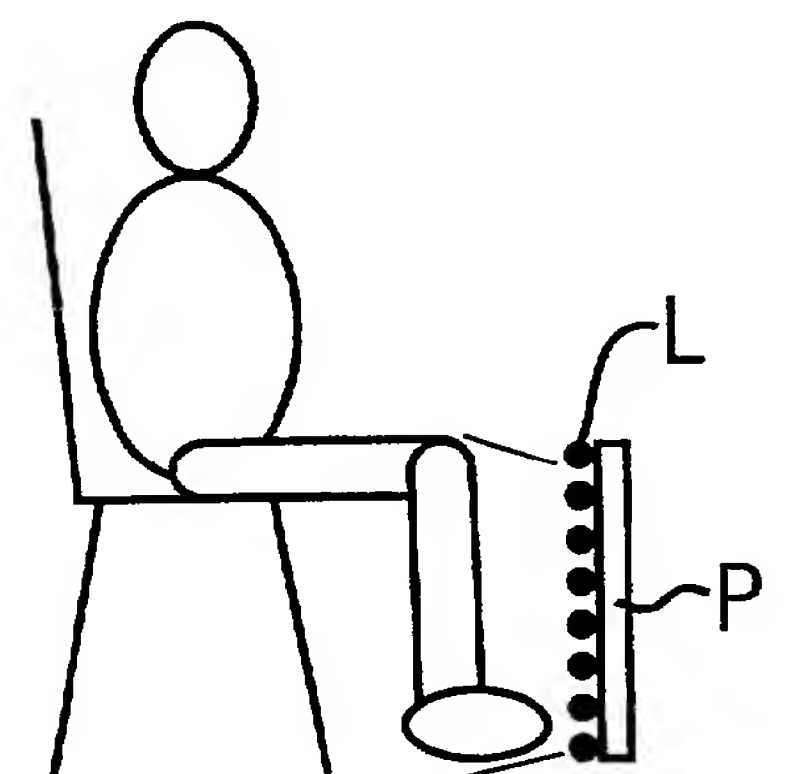


FIG. 14

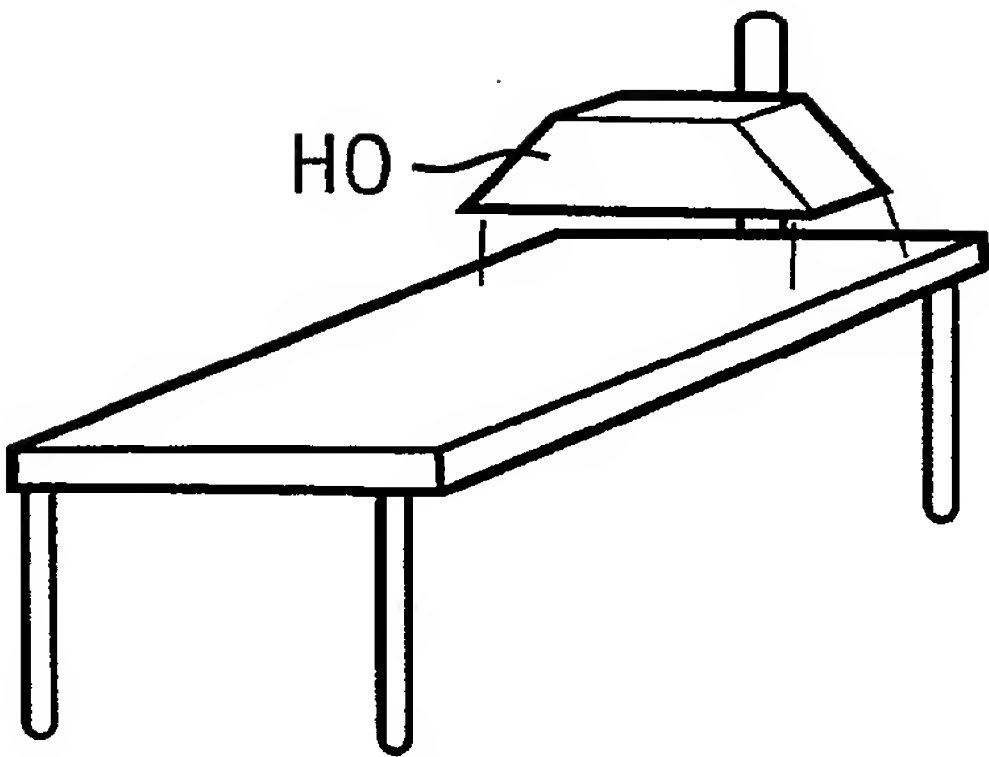


FIG. 15

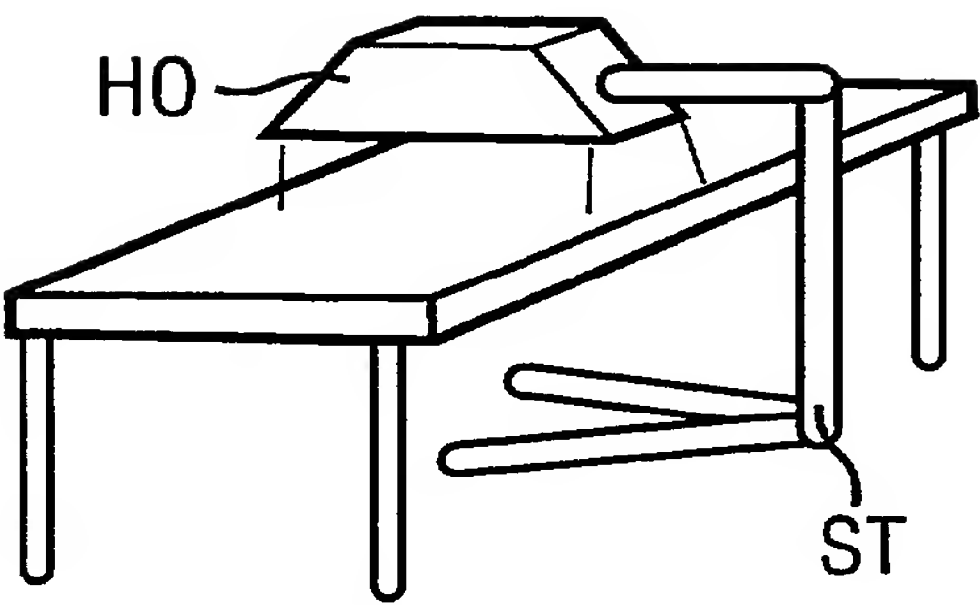


FIG. 16a

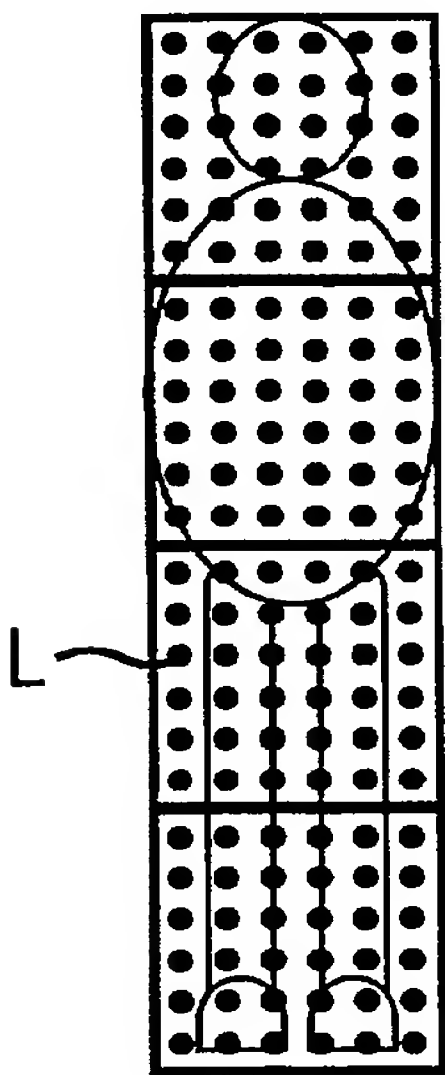


FIG. 16b

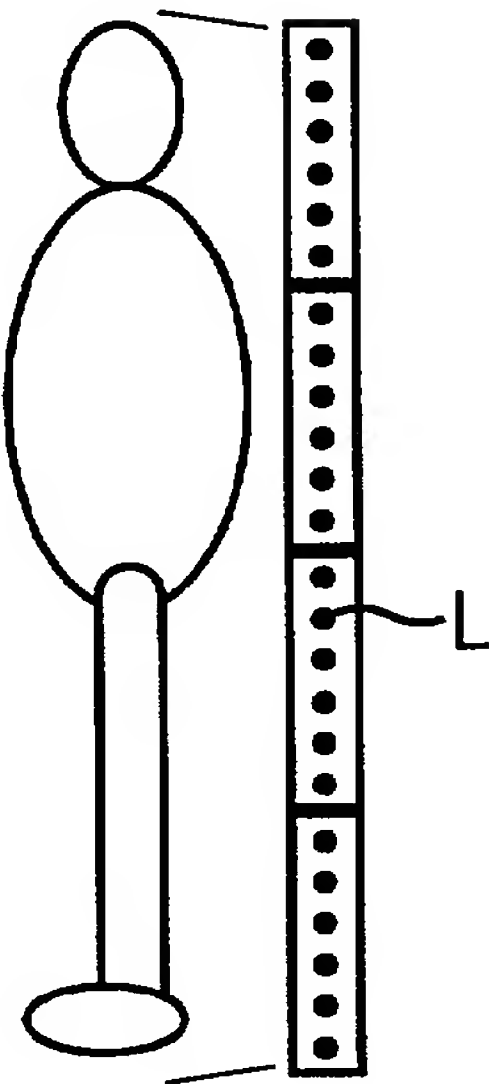


FIG. 17a

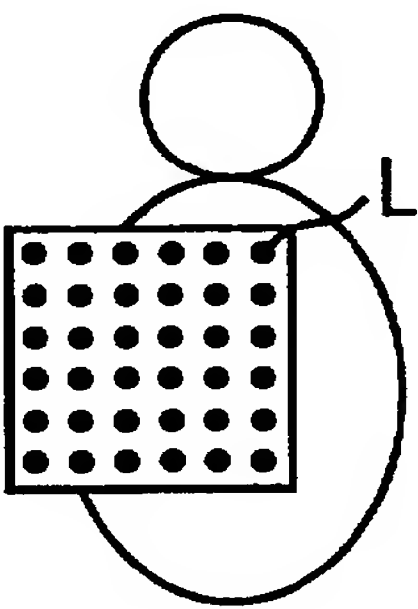


FIG. 17b

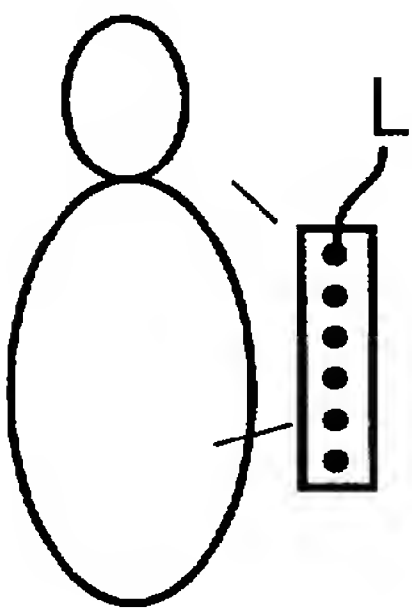


FIG. 18a

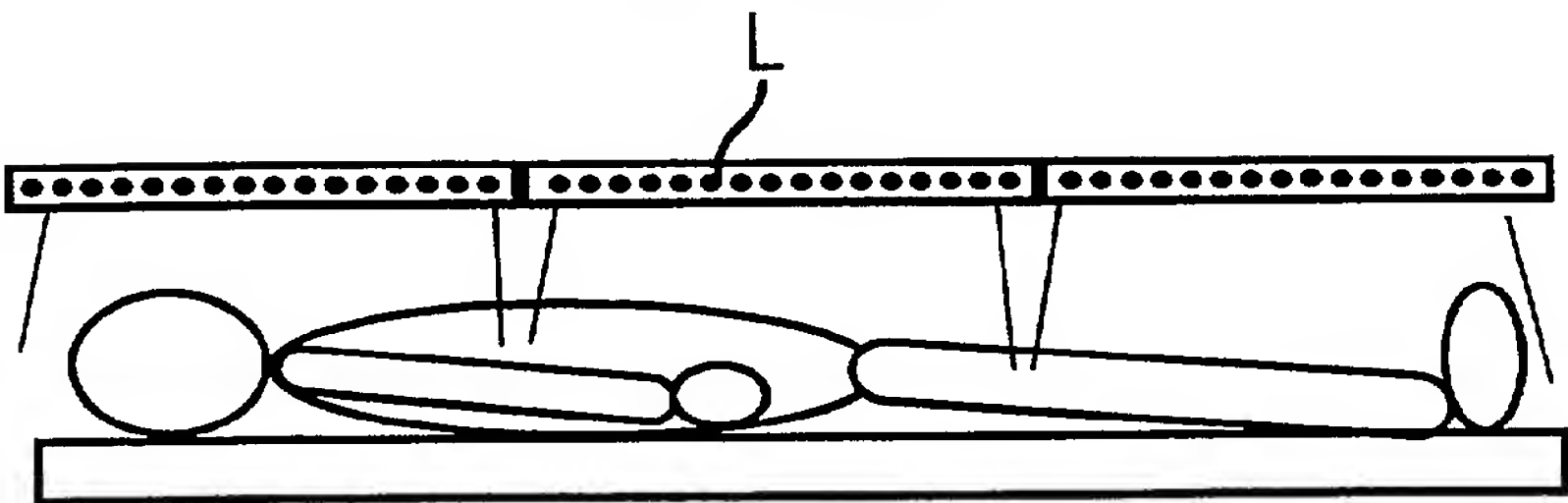


FIG. 18b

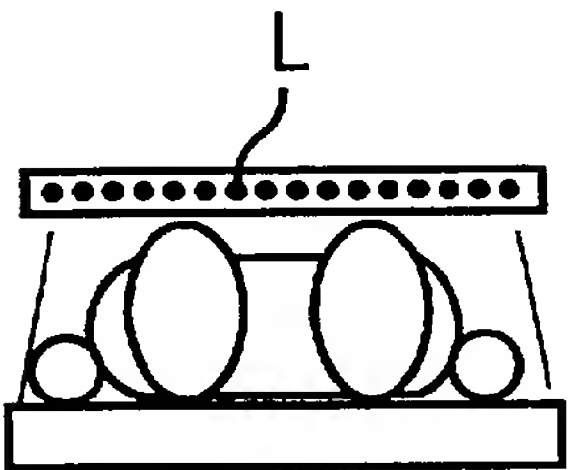


FIG. 19a

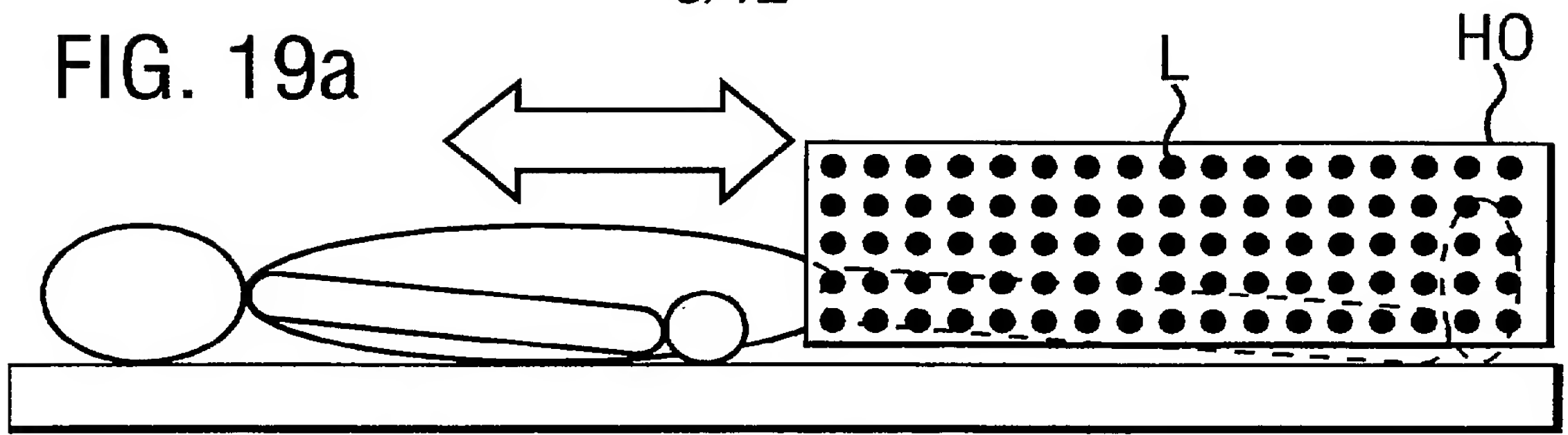


FIG. 19b

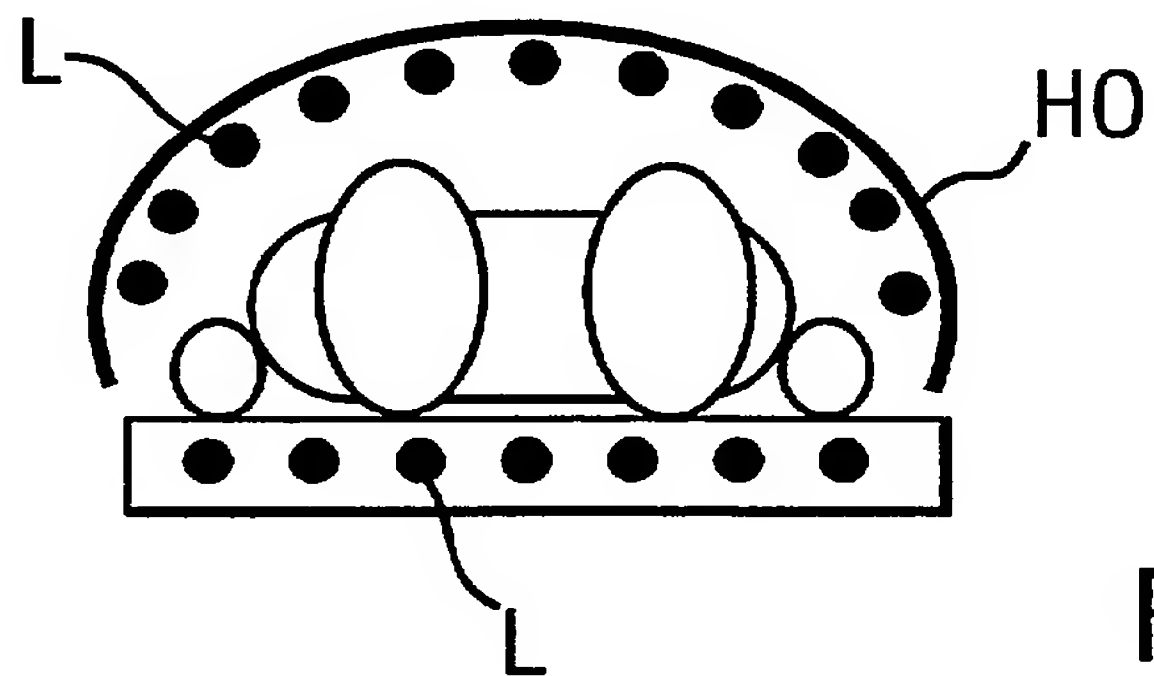


FIG. 20a

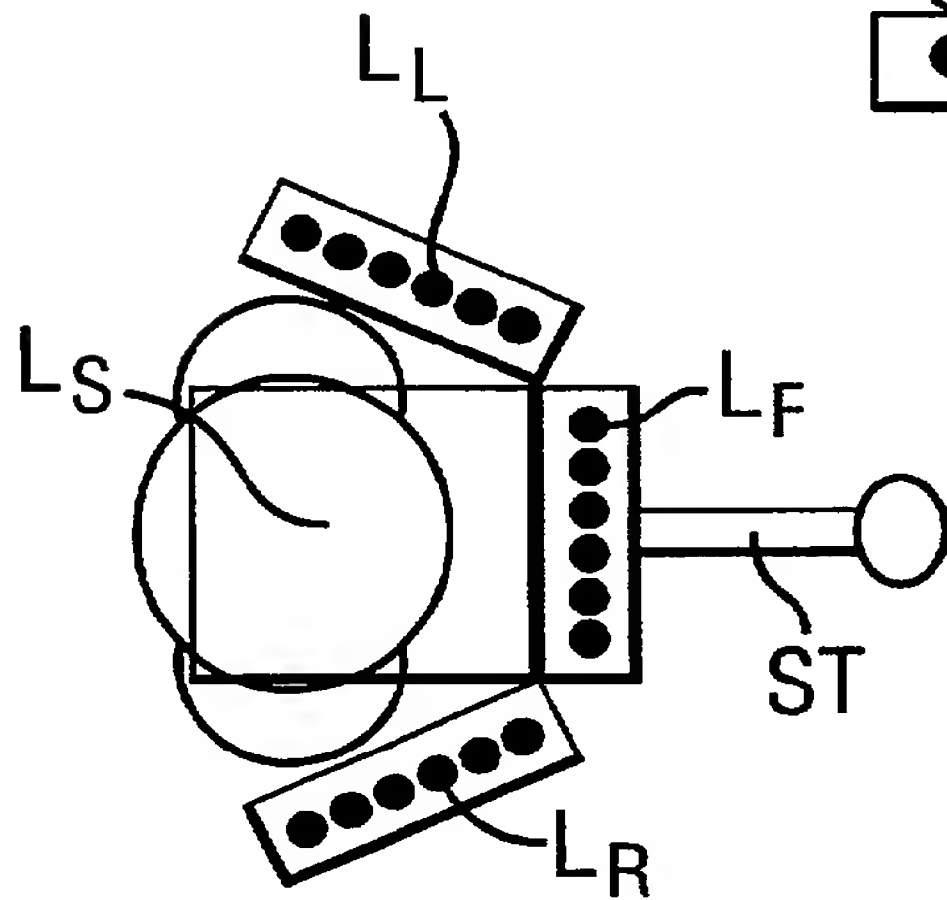


FIG. 20b

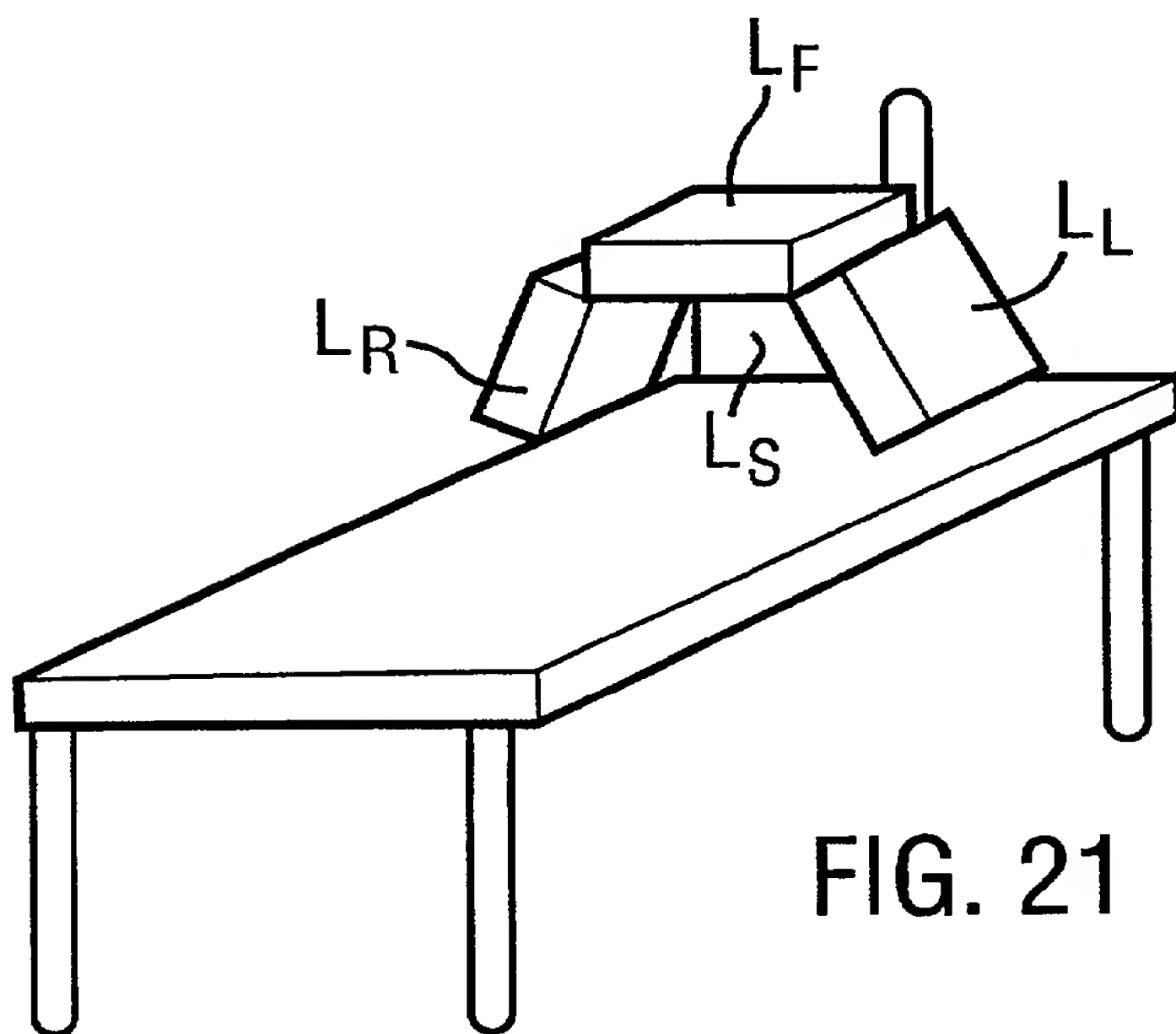
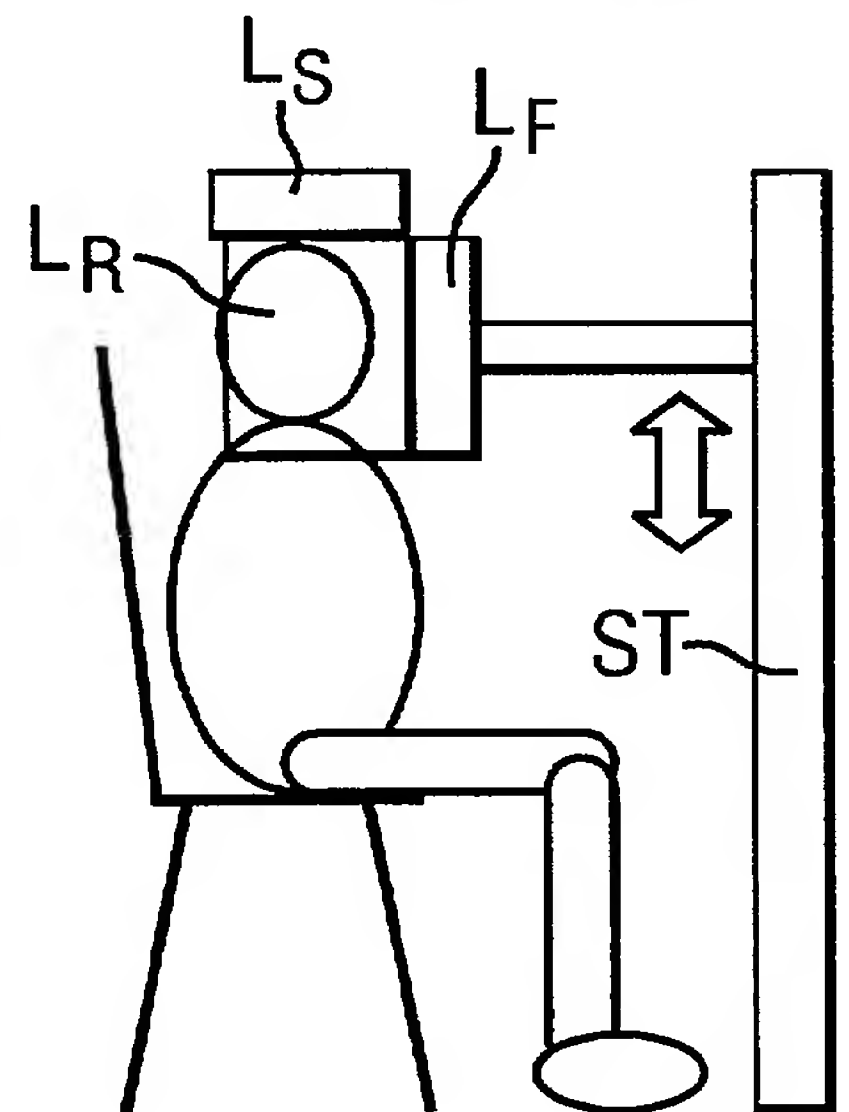


FIG. 21

FIG. 22a

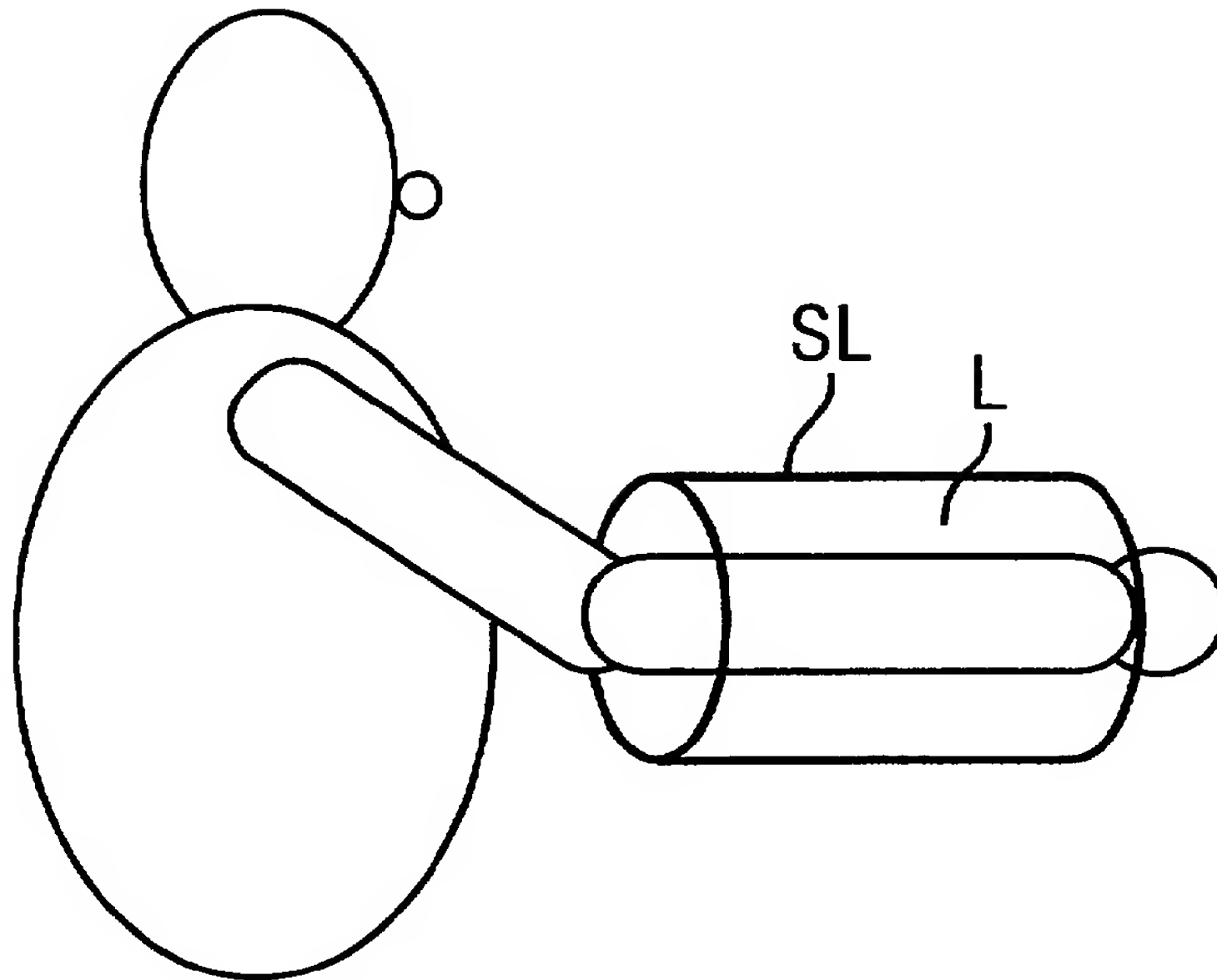


FIG. 22b

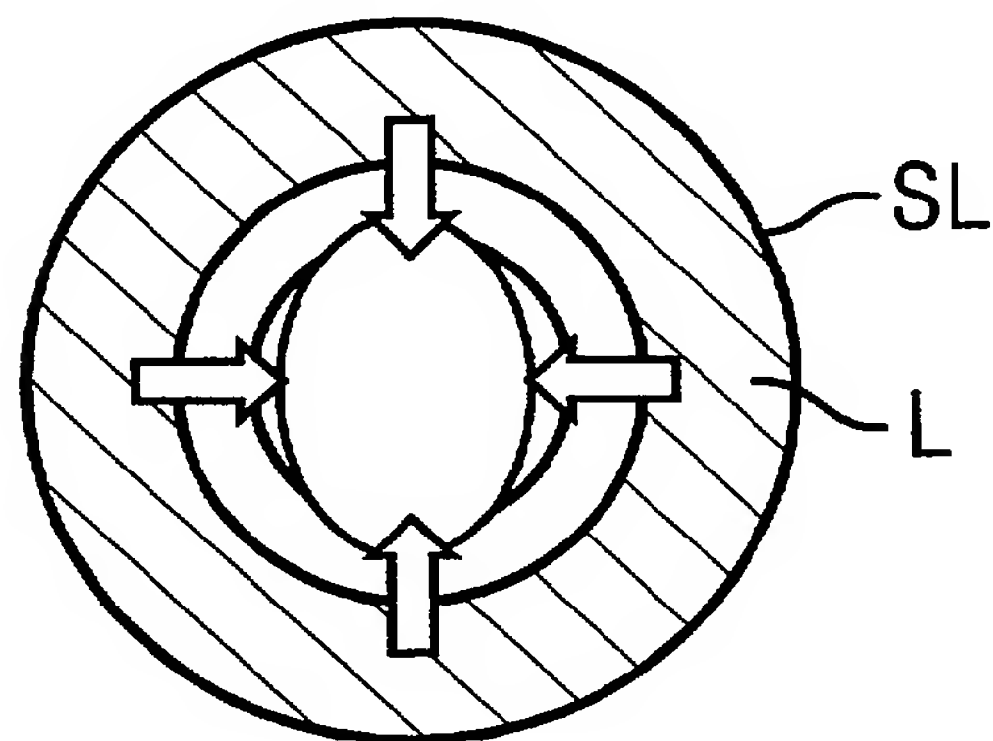


FIG. 22c

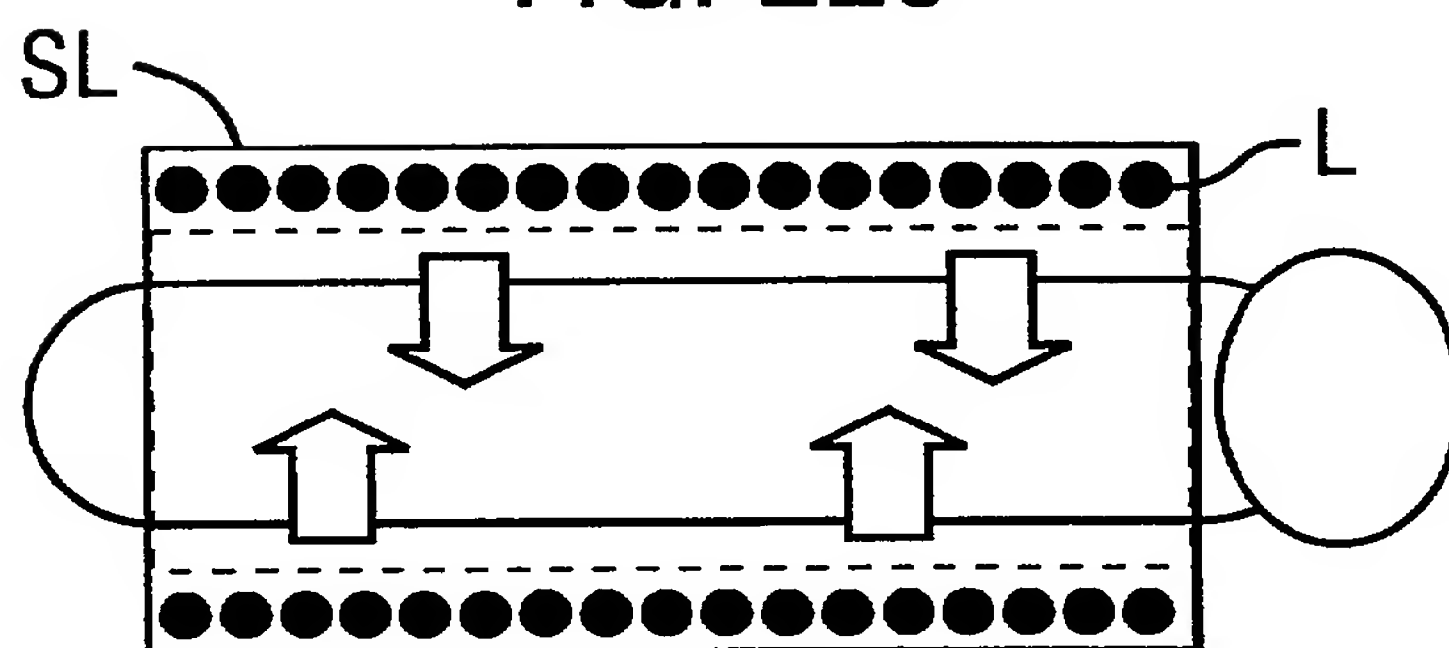


FIG. 23a

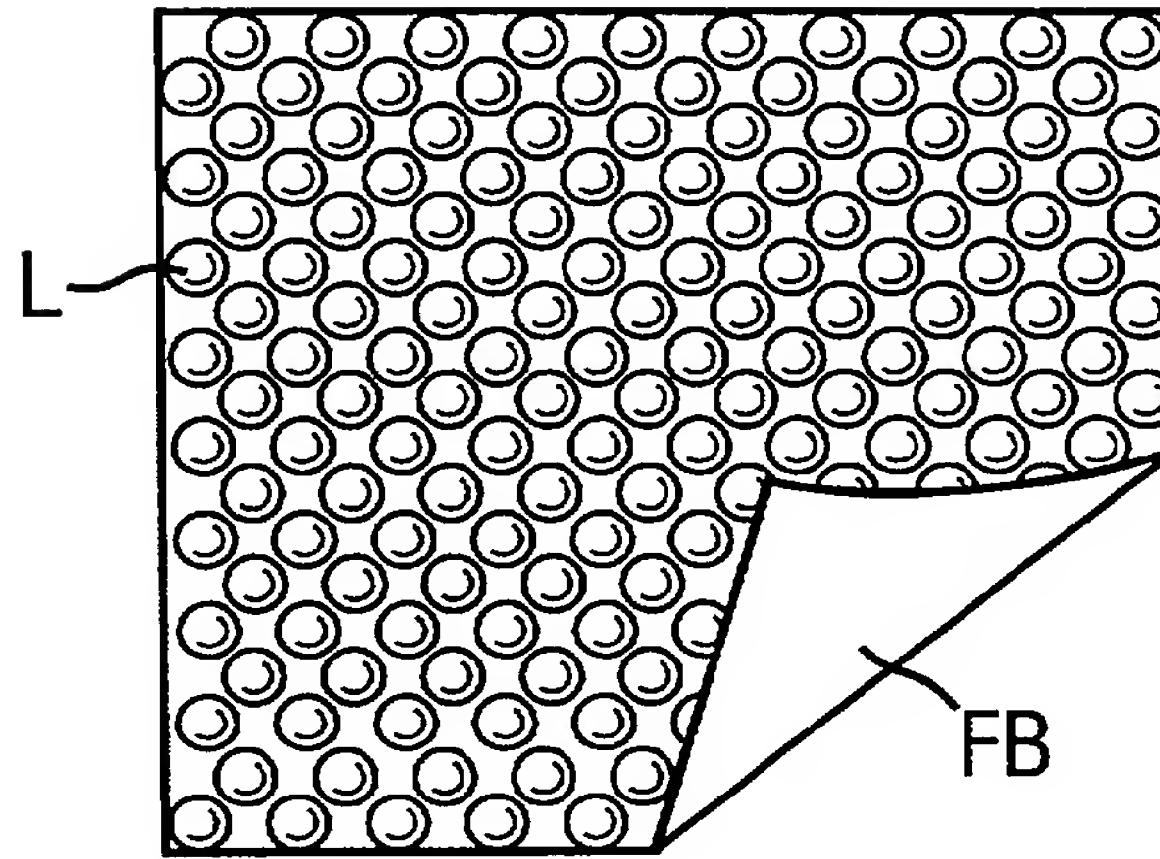


FIG. 23b

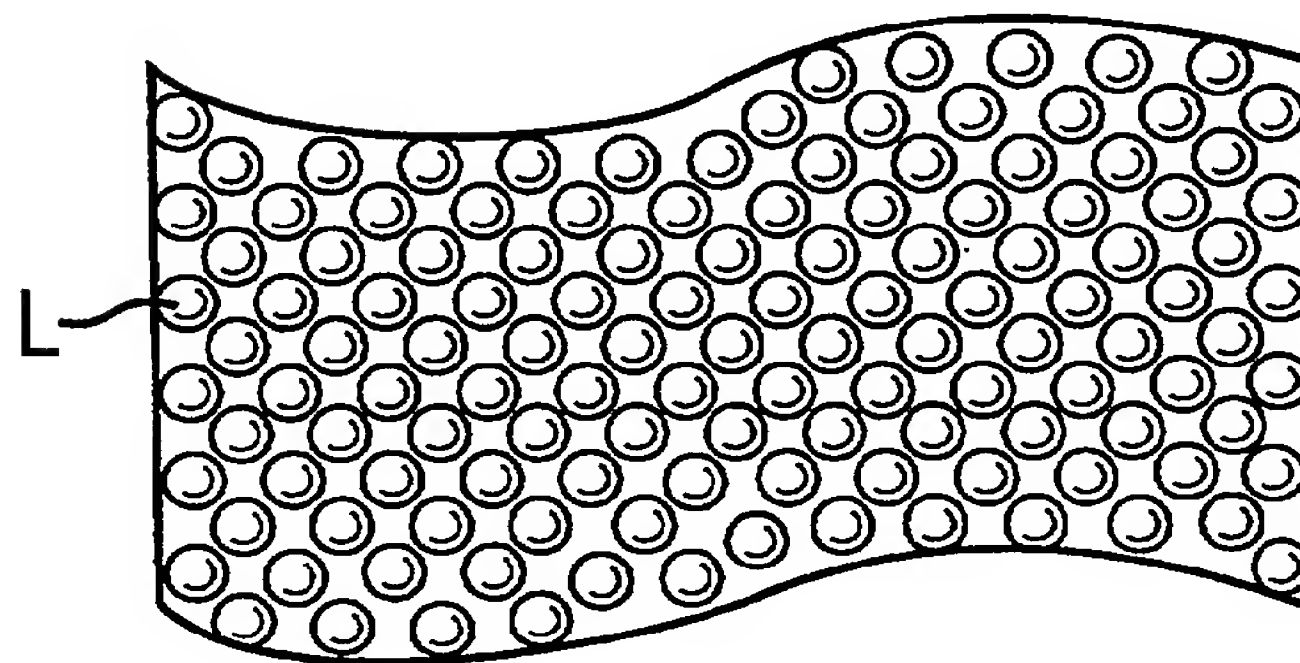


FIG. 23c

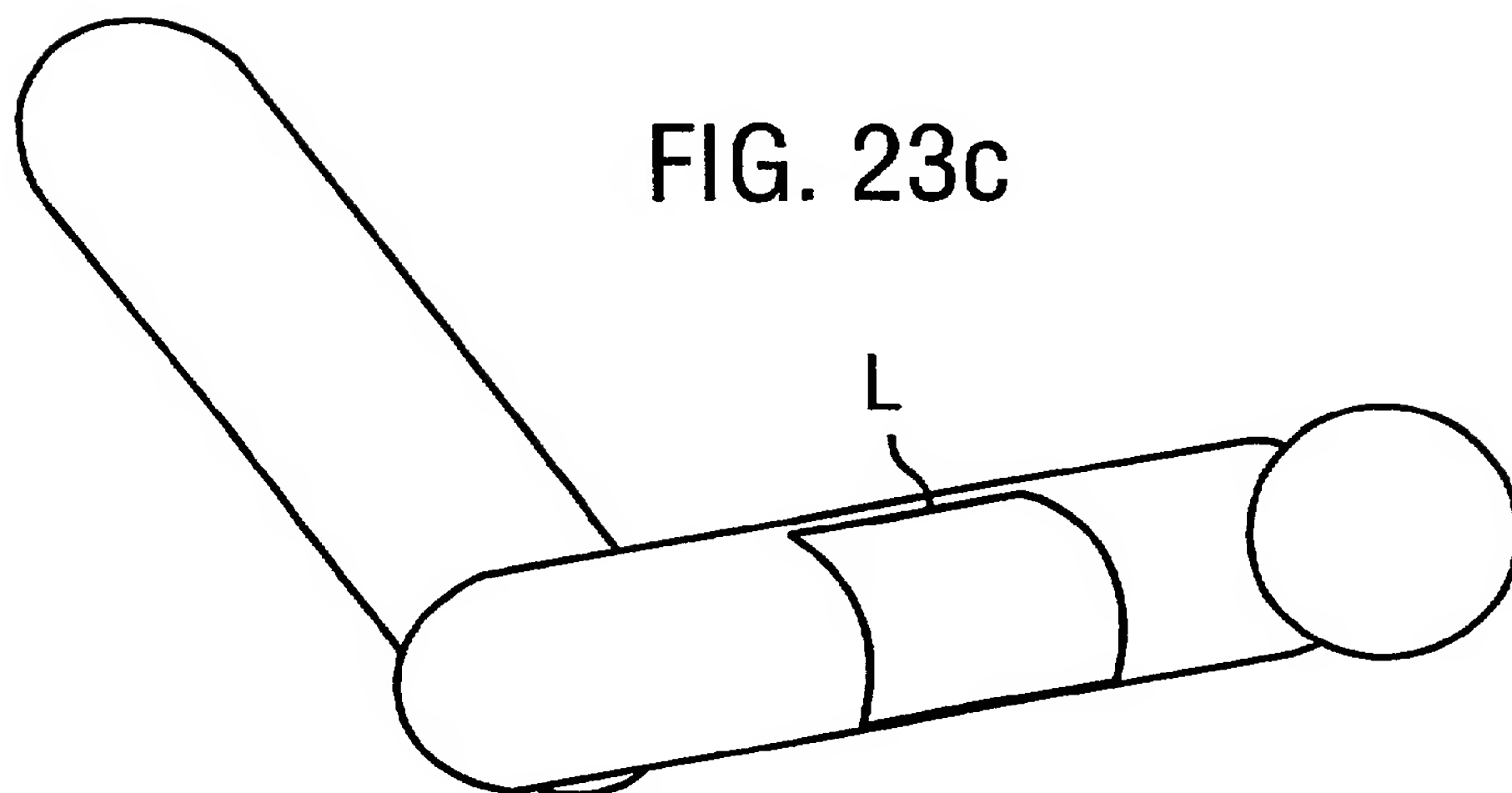


FIG. 24

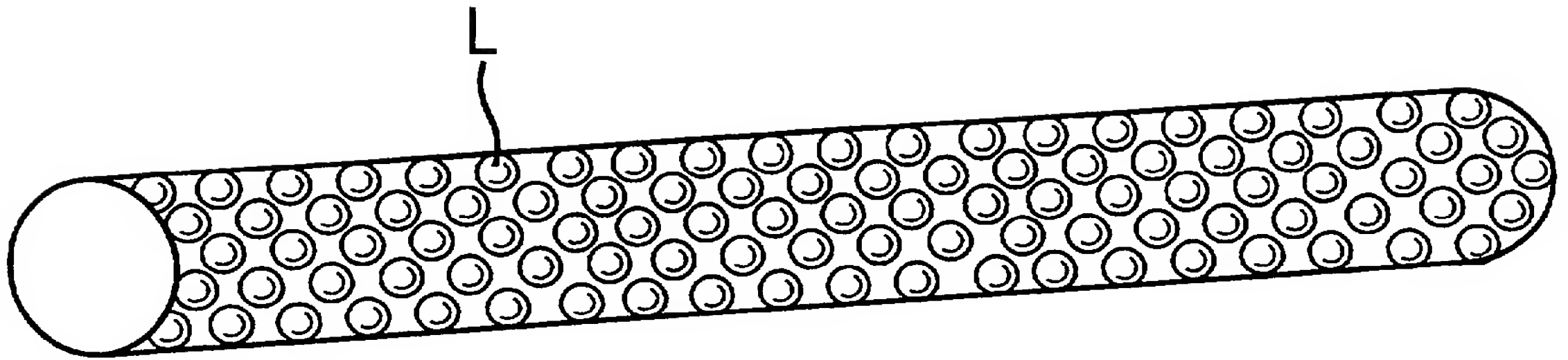


FIG. 25

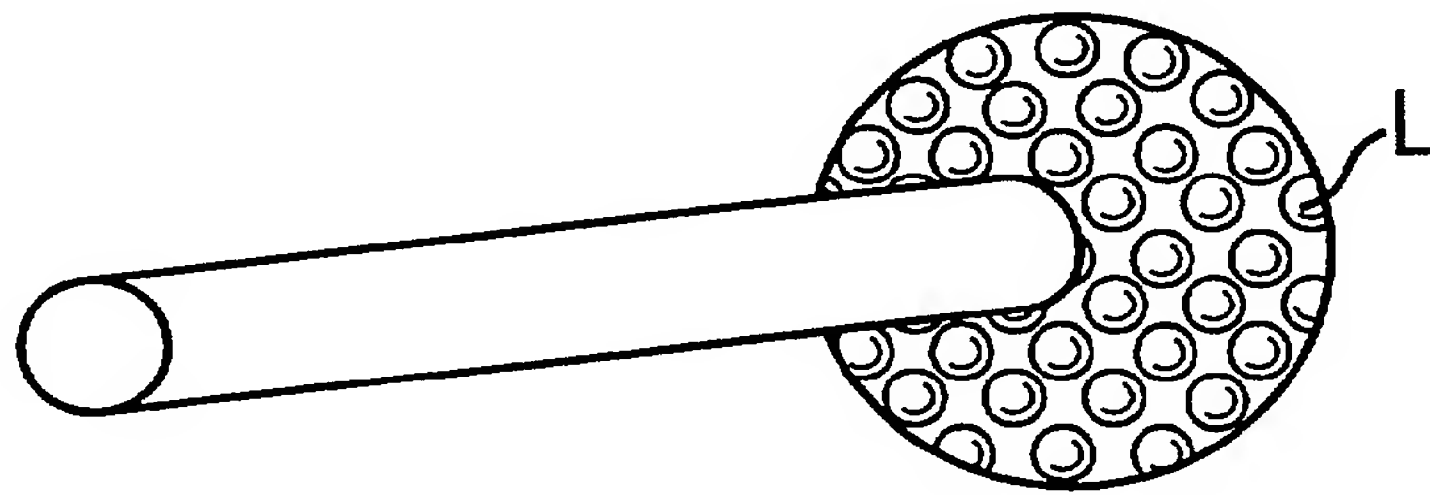
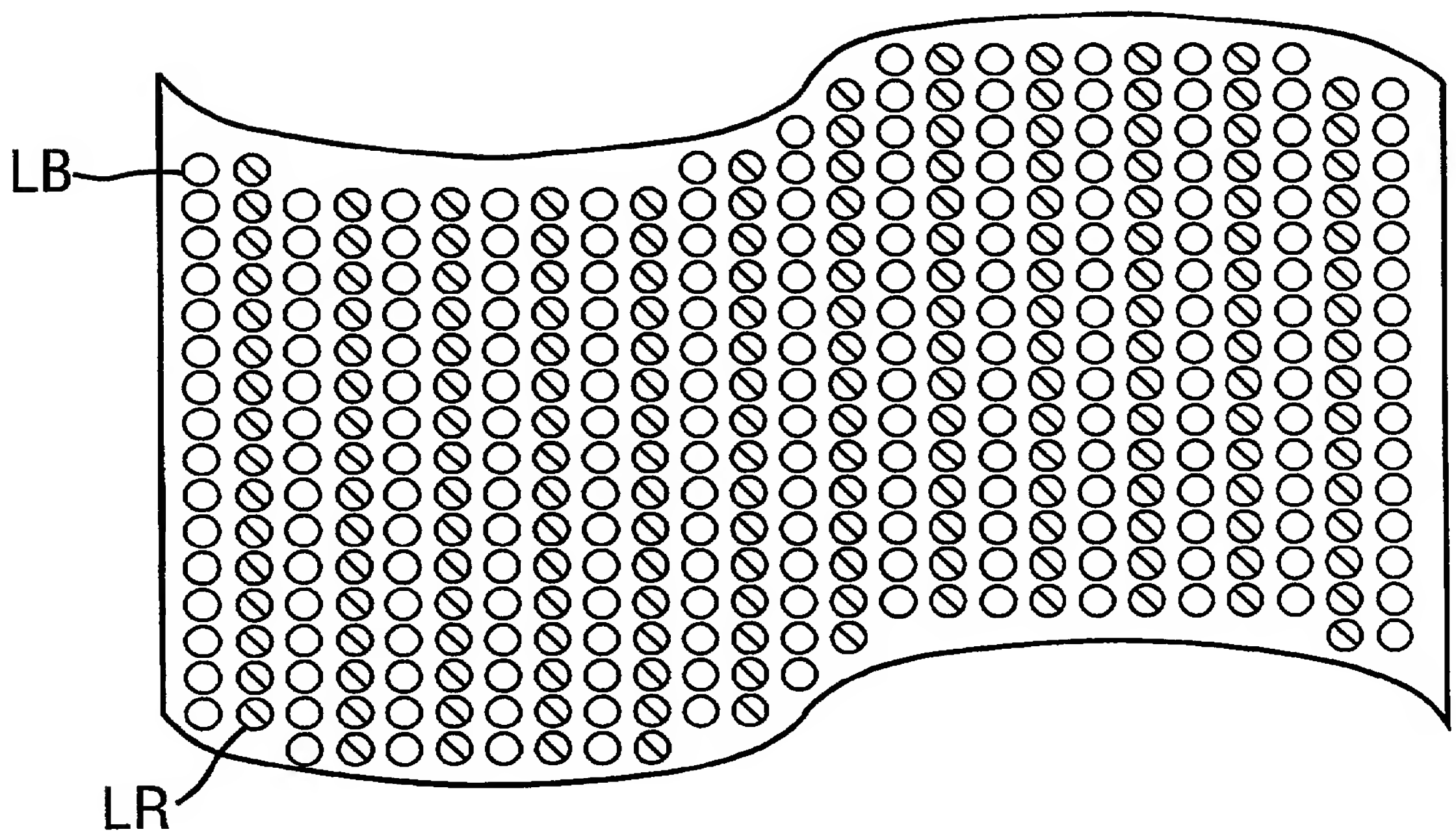


FIG. 26



THERAPEUTIC LIGHT SOURCE AND METHOD

The present invention relates to a non-coherent light source for use in therapy such as photodynamic therapy (PDT), particularly using light emitting diodes (LED's).

5 Photodynamic therapy involves the administration of a photosensitising drug to an affected area, and its subsequent irradiation with light - see for example 'The Physics of Photodynamic Therapy' by B C Wilson and M S Patterson, Physics in Medicine & Biology 31 (1986) April No. 4, London GB.

10 The document GB 2,212,010 discloses a therapeutic light source which uses an array of discrete LED's as an alternative to lasers or laser diodes. The output of the LED's is focussed so as to provide the necessary intensity.

 The document WO 94/15666 discloses a therapeutic light source
15 specifically for PDT, with an integrated array of LED's mounted on the distal end of a hand piece. The LED's are overdriven to give the necessary intensity, and cooled by the flow of water around a closed loop passing along the hand piece. The document US 5728090 discloses a somewhat similar device with various different types of head containing integrated LED matrices. These
20 devices require complicated liquid cooling circuits which would add to the cost of the device and add to the bulk of the hand piece, which is disadvantageous for invasive use.

 The document US 5728090 mentions that the wavelength of the LED's is between 300 nm and 1300 nm and is selected based upon the
25 particular photosensitive dye used during PDT. However, the wavelengths of LED's capable of providing the necessary intensity for PDT cannot freely be chosen within that range.

 According to one aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a non-planar array of

light-emitting diodes conforming with the shape of an external area to be treated or diagnosed.

According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a first array of light-emitting diodes and a second array of light emitting diodes movably connected thereto.

According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on the curved inner surface of a housing arranged to cover at least part of the length of a patient.

According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a housing, and an aperture allowing a part of the patient's body to be inserted into the housing, the array being arranged to direct light onto the part of the patient's body when inserted into the housing.

According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a sleeve so as to direct light onto part of an arm and/or hand of a patient when inserted into the sleeve.

According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an intraluminal probe carrying on the surface thereof an array of discrete light-emitting diodes.

According to another aspect of the present invention, there is provided a therapeutic light source comprising an air-cooled array of LED's, the air being vented in the vicinity of the array. In one embodiment, the array is mounted at the distal end of a hand piece suitable for invasive therapy.

According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's coupled to a light

guide for delivering the light to the area to be treated. Preferably, the LED's are directly coupled without intervening optical devices.

According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with emission spectra substantially limited to the range 550 to 660 nm, and preferably to one of the
5 ranges 590 to 640 nm, 560 to 644 nm, 650 to 660 nm, and 550 to 570 nm.

According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with peak emission spectra of approximately 430 nm, 470 nm, 505 nm or 525 nm.

10 Specific embodiments of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a diagram of a parallel-series matrix of discrete LED's used in first and second embodiments of the present invention;

Figure 2 is perspective diagram of the first embodiment;

15 Figure 3 is a cross section of part of the first embodiment;

Figure 4 is a graph showing the variation of intensity in a cross-section of the output of the first embodiment;

Figure 5 is a cross-sectional diagram of a second embodiment;

Figure 6 is a cross-sectional diagram of a third embodiment;

20 Figure 7 is a cross-sectional diagram of a fourth embodiment;

Figure 8 is a cross-sectional diagram of a fifth embodiment;

Figure 9 is a graph showing the absorption spectrum of PpIX and the emission spectra of two examples of LED's suitable for use with the
embodiments;

25 Figures 10a and 10b are side and front views respectively of an LED array in a sixth embodiment for treatment of the face;

Figures 11a, 11b and 11c are a cross-section in the plane of the patient's arm, a top view and a vertical cross-section transverse to the patient's arm of an LED array in a seventh embodiment for treatment of the
30 elbows of a patient;

Figure 12 is a side view of an LED array in an eighth embodiment used for treatment of the foot or feet;

Figure 13 is a side view of an LED array in a ninth embodiment used for treatment of the lower leg;

5 Figures 14 and 15 show arrangements of an LED array in tenth and eleventh embodiments for treatment of respectively the face and a section of a patient lying on a bed;

10 Figures 16a and 16b show respectively front and side views of a set of similar LED arrays in an twelfth embodiment for treatment of one side of a patient;

Figures 17a and 17b show respectively front and side views of an LED array in a thirteenth embodiment for treatment of a section of one side of a patient;

15 Figures 18a and 18b are respectively side and end views of a set of similar LED arrays in a fourteenth embodiment, for treatment of one side of a patient lying down;

Figures 19a and 19b are respectively side and end views of an LED array in a fifteenth embodiment for treatment of a section of a patient lying down;

20 Figures 20a and 20b are top and side views respectively of an arrangement of LED arrays in a sixteenth embodiment for treatment of the face and/or scalp;

Figure 21 shows a similar arrangement to that of Figures 20a and 20b, in a seventeenth embodiment for treatment of the face and/or scalp of a patient
25 lying down;

Figures 22a, 22b and 22c show respectively a side view, a transverse cross-section and a longitudinal cross-section of an LED array arranged within a sleeve in a eighteenth embodiment, for treatment of the hand, forearm and/or elbow;

Figures 23a, 23b and 23c show respectively two different shapes of flexible LED array, and a flexible array applied as a patch onto the skin of a patient, in an nineteenth embodiment;

Figure 24 shows an LED array arranged on the side of a cylindrical intraluminal probe in a twentieth embodiment;

Figure 25 shows an LED array arranged on the surface of a spherical intraluminal probe in a twenty-first embodiment; and

Figure 26 shows a more specific example of the flexible LED array in the nineteenth embodiment.

In a therapeutic light source in the first embodiment, as illustrated in Figures 1 to 5, light is emitted from a parallel-series matrix of LED's L connected through a current-limiting resistor R to a source of a voltage +V. The LED matrix is mounted on a heatsink array H parallel to and spaced apart from a fan array F by support rods R. Air is blown by the fan array F onto the back of the heatsink array H.

As shown in more detail in Figure 3, the heatsink array H comprises a plurality of individual heatsinks h mounted on the ends of the legs of the LED's, which pass through a support plate P. Each leg is soldered to an adjacent leg of another of the LED's in the same column. The support plate P is perforated to allow air to flow more freely around the heatsinks h and the LED's L.

The LED's L are arranged so as to produce a substantially uniform illumination of $\pm 10\%$ or less across a treatment field by selecting the beam divergence and spacing of the LED's L so that their individual beams overlap without causing substantial peaks or troughs in intensity. In the example shown in Figure 4, uniformity of $\pm 6\%$ is achieved. In this embodiment, no optical system is needed between the LED's and the patient; instead, the light is emitted directly from the LED's onto the patient. As the light is not concentrated by any optical system, the LED's have individual power outputs of at least 5 mW and preferably at least 10 mW, to give the necessary fluence

rates in the treatment field of at least 30 mW/cm^2 in the red region of the spectrum and at least 10 mW/cm^2 in the blue region.

5 In one specific example, a 15 cm diameter array of 288 'Super flux' LED's was used to produce a total light output of 8 W at 45 mW/cm^2 in the treatment field. The LED's were driven at a higher current load than their specification while being cooled by forced air convection from the fans F. In the specific example, the current was limited to 90 mA per column of diodes, but may be increased to 120 mA or more if increased light output is needed. The number of diodes in series, in each column, is selected so that the total
10 forward operating voltage is as close as possible to, but less than, the power supply output voltage, in this case 48 V. This arrangement avoids wasteful in-circuit heating and maximizes the operating efficiency of the electrical system.

A method of treatment for oncological and non-oncological skin diseases such as cases of actinic/solar keratoses, Bowen's disease, superficial
15 basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, eczema, psoriasis, nevus sebaceous, gastrointestinal conditions (e.g. Barratt's oesophagus and colorectal carcinomas), gynaecological disorders (e.g. VIN, CIN and excessive uterine bleeding), oral cancers (e.g. pre-malignant or dysplastic
20 lesions and squamous cell carcinomas), viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata, or hirsutism, using the first embodiment, will now be described. A cream or solution containing a photosensitising drug such as 5-ALA is applied topically under medical supervision to the affected
25 area of the skin of the patient, or administered intravenously or orally. In another method of application for large areas, the patient may be immersed in a bath of solution. The affected area may then be covered for a period of 3 to 6 hours, or up to 24 hours if the treatment is to be continued the next day, to prevent removal of the drug and carrier, or activation by sunlight. The area is
30 then uncovered and exposed to light from the lamp according to the first

embodiment for a period of 15 to 30 minutes. The treatment may then be repeated as necessary, for a total of 1 to 3 treatments. This method is particularly suitable for the treatment of patients with very large lesions or multiple lesions extending over a large area.

5 In a method of treatment using the device of the first embodiment, the LED array is positioned approximately parallel to an external affected area of a patient to be treated, with a separation sufficient to achieve the uniform illumination as shown in Figure 4, for example 2 to 5 cm. The device may also be used for cosmetic or partially cosmetic treatment with a
10 photosensitizing drug for portwine stain removal and hair restoration/removal, and without a photosensitizing drug for skin rejuvenation, wrinkle removal or biostimulation (including wound healing).

 The lamp may also be used for fluorescence detection (photodiagnosis).

15 The first embodiment may be modified in a second embodiment, as shown in Figure 5, by the addition of a frusto-conical waveguide W, for example of acrylic (e.g. Perspex™) or glass, supported by the support rods R, which are extended in this embodiment. The waveguide W is arranged to concentrate light emitted by the LED's onto a smaller area with higher
20 intensity. This arrangement is suitable for treating smaller external surfaces.

 The second embodiment may be modified in a third embodiment, as shown in Figure 6, to deliver the light from the waveguide W into a lightguide L for internal treatment. The lightguide L, such as an optical fibre or fibre bundle, or liquid light guide, is held in a lightguide receptacle or adapter A,
25 that is compatible for example with Olympus, Storz, ACMI or Wolf light cable fittings, in abutment or immediately adjacent relation with the narrow end of the waveguide W. The lightguide L may be of 3, 5 or 8 mm diameter. The support rods R align the optical axes of the waveguide W and lightguide L, so that the light emitted by the waveguide W is launched into the lightguide
30 L. In the third embodiment, the light is concentrated by the waveguide and

emitted over a small area at the distal end of the lightguide L which may be inserted into body cavities for oral, gynaecological, gastrointestinal or intraluminal treatment.

The third embodiment may be modified in a fourth embodiment, as shown in Figure 7, in which the discrete LED array is replaced by an integrated multi-die LED matrix IM (for example part no. OD 6380, OD 6624 or OD 6680 available from AMS Optotech, Bristol, UK) mounted on the support plate/heatsink P, H. A Peltier effect thermoelectric cooler PC is mounted in thermal contact with the opposite side of the support plate P, the heated side of which is cooled by the fan F. The proximal end of the lightguide L is directly adjacent or abutting the integrated LED matrix IM, which are of similar cross-section so that the waveguide is not needed to launch the emitted light into the lightguide L.

A fifth embodiment, as shown in Figure 8, is designed specifically for treatment of the cervix, such as PDT treatment. The fifth embodiment has the form of a hand piece having a hollow stem S, for example of acrylic or polycarbonate, through which air is blown at low pressure by a fan F mounted at the proximal end. The distal end has a head portion HP comprising a housing within which is mounted a discrete LED array mounted on a support plate/heatsink P/H. Air passes through the hollow stem S onto the heatsink H so as to extract heat therefrom and is then vented through apertures AP on the proximal side of the housing. The distal end of the housing is concave and dimensioned so as to fit closely over the end of the cervix C. A transparent end window W, for example of acrylic or glass, prevents infiltration of the LED's. Power is carried to the LED's through wires (not shown) mounted on the wall of the acrylic stem S. In use, the hand piece is positioned so that the distal end fits over the cervix of the patient and is clamped in position for the duration of the treatment.

The selection of appropriate discrete LED's for PDT using any of the first to fourth embodiments will now be described, grouped according to die material.

A first suitable type of LED is based on aluminium indium gallium phosphide/gallium phosphide (AlInGaP/GaP) of transparent substrate (TS) or absorbing substrate (AS) type. The output wavelengths are in the range 590 to 640 nm with peak emission wavelengths of 590, 596, 605, 615, 626, 630 and 640 nm. Commercially available examples are the 'SunPower'TM or 'Precision Optical Power'TM series from Hewlett Packard Company, designed for use in the automotive industry, for commercial outdoor advertising and traffic management. Suitable LED's are those packaged as: SMT (surface mount technology) e.g. HSMA, HSMB, HSMC, HSML series and preferably HSMB HR00 R1T20 or HSMB HA00R1T2H; Axial e.g. HLMA or HLMT series; T1 e.g. HLMP series, preferably HLMP NG05, HLMP NG07, HLMP J105; T13/4 e.g. HLMP series, preferably HLMP DG08, HLMP DG15, HLMP GG08, HLMP DD16; SuperfluxTM e.g. HPWA or HPWT series, preferably HPWA (MH/DH/ML/DL) 00 00000, HPWT (RD/MD/DD/BD/RH/MH/DH/BH/RL/ML/DL/BL) 00 00000, most preferably HPWT (DD/DH/DL/MH/ML/MD) 00 00000; SnapLEDTM e.g. HPWT, HPWS, HPWL series, preferably HPWT (SH/PH/SL/PL) 00, HPWT (TH/FH/TL/FL) 00 or HPWS (TH/FH/TL/FL) 00. Suitable products from other manufacturers include: of SMT type, Advanced Products Inc. (API) part no. HCL4205AO; of T1 type, American Bright Optoelectronics (ABO) part no. BL BJ3331E or BL BJ2331E; of Superflux type, ABO part no.'s BL F2J23, BL F2J33 and BL F1F33.

A second suitable type of LED is the aluminium indium gallium phosphide/gallium arsenic (AlInGaP/GaAs) type, with emission wavelengths in the range 560 to 644 nm and peak emission wavelengths of 562 nm, 574 nm, 590 nm, 612 nm, 620 nm, 623 nm and 644 nm. Examples commercially available from Toshiba in T1 package are the TLRH, TLRE, TLSH, TLOH or

TLYH series, preferably TLRH 262, TLRH 160, TLRE 160, TLSH 1100, TLOH 1100, TLYH 1100 or S4F4 2Q1; or in T13/4 package are the TLRH or TLSH series, preferably TLRH 180P or TLSH 180P. Another example is Kingbright L934SURC-E.

5 A third suitable type of LED is aluminium gallium arsenic type (AlGaAs), with emission wavelengths in the range 650 to 660 nm. Examples in T1 package include the Toshiba TLRA series, preferably TLRA 290P or TLRA 293P, and Kingbright L934 SRCG, L934 SRCH, and L934 SRCJ and in T13/4 package include Kingbright L53 SRCE.

10 A fourth suitable type of LED is gallium phosphide (GaP) type, with emission wavelengths in the range 550 to 570 nm.

 A fifth suitable type of LED is indium gallium nitride (InGaN). In the type with an emission wavelength of 525 nm, commercially available examples include: in SMT package, API's HCL 1513AG; and in T1 package, 15 Farnell's #942 467, Radio Spare's #228 1879 and #249 8752, API's HB3h 443AG and Plus Opto's NSPG500S. In the type with emission wavelengths of 470 and 505 nm and T1 package type, examples are Farnell's #142 773, Radio Spare's #235 9900 and American Bright Optoelectronics Inc.'s BL BH3PW1.

20 A sixth suitable type of LED is gallium nitride/silicon (GaN/Si), with an emission wavelength of 430 nm. One commercial example is Siemens LB3336 (also known as RS #284 1386).

 Each of the above LED types is selected to have an emission spectrum substantially coincident with the absorption spectrum of one or more of the following common photosensitizers given below in Table 1, and therefore 25 embodiments having such LED's are suitable for PDT. For example, Figure 9 shows the absorption spectrum of PpIX, including peaks at 505nm, 545 nm, 580 nm and 633 nm. Inset are the emission spectra, in units of peak intensity and on the same wavelength axis, of LED part no. HPWA DL00 with a peak at 590 nm and LED part no. HPWT DH00 with a peak at 630 nm, the peaks

having sufficient breadth to give a substantial overlap with the 580 nm and 633 nm peaks respectively in the absorption spectrum of PpIX.

Table 1

Photosensitizer	Red absorption Band (nm)	Red Peak (nm)	Blue/Green Peak (nm)
Naphthalocyanines	780-810		
Chalcogenopyriliium dyes	780-820		
Phthalocyanines (e.g. ZnII Pc)	670-720	690	
Tin etiopurpurin (SnET ₂)	660-710	660-665	447
Chlorins (e.g. N-Aspartyl chlorin e6 or NPe6)	660-700	664	
Benzoporphyrin derivative (BPD)		685/690	456
Lutetium texaphrin (Lu-TeX)		735	
Al(S ₁ /S ₂ /S ₃ /S ₄) Pc	660-710	670/685	410, 480
Photofrin		625/630	405
Protoporphyrin IX (PpIX) - from 5/ δ Aminolaevulinic Acid (5ALA)		635	410, 505, 540, 580
Tetra m-hydroxyphenyl Chlorin (mTHPC)		650	440, 525

5

The discrete LED array may comprise more than one different type of LED, each with different emission spectra, selected to match different absorption bands of the selected photosensitizer. Each type of LED may be switched independently. The penetration depth (i.e. the depth at which the intensity has been attenuated to e^{-1}) may also be varied by switching on only one type of LED in the array so as to select a suitable emission band, since the penetration depth is a function of the wavelength.

10

The LED array may be composed of individually switchable spatially distinct segments of LED's. Selected segments may be switched on so as to treat a selected area of the patient within the overall area of the matrix array.

5 The lamp may include an electro-optical detector arranged to monitor the light dose delivered and to switch off the light emission when a target dose is reached. Alternatively, or additionally, the detector is arranged to monitor the instantaneous light intensity and to vary the electrical power supplied to the tubes so as to maintain the intensity within predetermined limits, and/or to switch off the light emission if a maximum limit is exceeded.

10 Various different arrangements of LED array suitable for treatment of different areas of a patient will now be described. The LED's are discrete LED's as described above. Except where stated otherwise, the LED's may be fan-cooled using integrated fans.

15 Figures 10a and 10b show an array of LED's L in a sixth embodiment, arranged on a support P shaped as a curved visor for treatment of the face of a patient. The array is supported in front of the patient's face by a head band HB or other head wear worn by the patient.

20 Figures 11a to 11c show an array of LED's L in a seventh embodiment arranged within a cuboid housing HO which has two similar apertures AP on one face, to allow the elbows to be inserted into the housing HO. The edges of the apertures AP are cushioned to allow the arms to be rested comfortably. Within the housing HO is arranged a surface SU which is curved both in the plane of the arms and perpendicular to that plane, as shown in Figure 11c. The LED's L are mounted on this surface SU so that light emitted therefrom is
25 concentrated onto the elbows of the patient.

Figure 12 shows an LED array L in an eighth embodiment mounted on a support plate P, and covered by a transparent or translucent cover on which the foot or feet of the patient rest during treatment.

30 Figure 13 shows an LED array L in a ninth embodiment mounted on a support plate P and arranged for treatment of the lower leg of a patient.

Figures 14 and 15 show an LED array L, mounted in a housing HO in the form of a trapezoid prism, the upper inner surface carrying the LED array and the lower surface being open to allow light to fall onto the patient. The side faces may be reflective, or carry additional LED arrays. In the tenth embodiment shown in Figure 14, the housing HO is mounted at one end of a bed so that its height above the bed is adjustable, for facial treatment of a patient lying on the bed. In the eleventh embodiment shown in Figure 15, the housing HO is mounted on a stand ST and is adjustable in height, for treatment of a selected part of a patient lying on the bed.

Figures 16a and 16b show a series of four coplanar LED arrays L in a twelfth embodiment arranged to treat one side of a patient. Each of the arrays is independently switchable so that selected sections of the patient can be treated.

Figures 17a and 17b show a single LED array L in a thirteenth embodiment positioned to treat a section of the patient.

Figures 18a and 18b show a series of three coplanar LED arrays L in a fourteenth embodiment arranged to treat one side of a patient lying down. Each of the arrays is independently switchable so that selected sections of the patient can be treated.

Figures 19a and 19b show an array of LED's L in a fifteenth embodiment mounted on the inner surface of a curved housing HO for treatment of a patient lying on a further, planar array of LED's, for treatment of a section of the patient from all sides. The housing HO is slidable along the length of the patient so as to treat a selected area of the patient. Sections of the planar array of LED's are switchable so as to illuminate only the selected section.

Figures 20a and 20b show a sixteenth embodiment comprising a front-facial LED array L_F for directing light onto the face of the patient from the front, a scalp LED array L_S and left and right side-facial LED arrays L_L , L_R moveably connected, for example by hinges, to the front-facial array L_F , for

directing light onto the scalp, left side of the face and right side of the face respectively. The front-facial array L_F is slideably attached to a stand ST for vertical adjustment to the head height of the patient, preferably when sitting.

Figure 21 shows a seventeenth embodiment, similar to that of Figures 20a and 20b, except that it is arranged for facial and/or scalp treatment of a patient when lying down. The stand ST is mounted on a bed, instead of being free-standing, and the arrays are rotated by 90° so as to correspond to the position of the patient's head when lying down.

Figures 22a, 22b and 22c show an eighteenth embodiment in which an LED array L is mounted on the inner surface of a sleeve SL so as to direct light onto the hand, forearm and/or elbow within the sleeve.

Figures 23a and 23b show respectively a square and a rectangular LED array L in a nineteenth embodiment mounted on a flexible backing member FB which can be applied to an area of the patient to be treated, such as part of the forearm as shown in Figure 23c, with the LED's facing inwardly. The LED array thereby follows the contours of the area to be treated. The flexible backing member FB may be cooled by a fan which is either discrete or connected thereto by a flexible membrane which is fixed around the flexible backing member FB and directs air from a fan onto the backing member, through which the air is vented.

Figure 24 shows an LED array in a twentieth embodiment arranged on the surface of a cylindrical intraluminal probe, while Figure 25 shows an LED array in a twenty-first embodiment arranged on the surface of a spherical head of an intraluminal probes. The probes are dimensioned for vulval, cervical, endometrial, bladder, gastrointestinal, oral, nasal, aural and/or bronchial treatment.

In tests performed by the inventor, the efficacy of PDT using red (approximately 630 nm) emission from LED's was established in *in-vivo* comparative studies using a sub-cutaneous mammary tumour regrowth delay assay. Using radiobiological end-points, it was shown that the solid-state

prototype efficacies were comparable to that of expensive conventional lasers for PDT (i.e. no significant difference, $p=0.21$). These results were confirmed in further clinical studies in the treatment of Bowen's disease and basal cell carcinomas where comparative complete response rates were achieved as compared to laser PDT.

Figure 26 shows a more specific example of the nineteenth embodiment, consisting of rows of blue LED's L_B interspersed with rows of red LED's L_R so as to form a discrete LED array composed of different types of LED as described above. The blue LED's L_B are switchable on and off together, independently of the red LED's L_R which are also switchable on and off together. In this way, red or blue illumination may be chosen according to the type of treatment and penetration depth required.

The blue LED's have an emission spectrum substantially (for example full width half maximum bandwidth) in the range 370 to 450 nm, and preferably 400 to 430 nm. This range is particularly suitable for the treatment of pre-cancerous conditions, in particular actinic keratoses.

The red LED's have an emission spectrum substantially (for example full width half maximum bandwidth) in the range 620 to 700 nm. This range is particularly suitable for the treatment of non-melanoma, such as basal cell or squamous cell carcinoma, or mycosis fungoides.

CLAIMS

1. A light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on a flexible backing, the array including light-emitting diodes of a first type having a first emission spectrum and light-emitting diodes of a second type having a second emission spectrum different from the first emission spectrum.
2. A light source according to claim 1, wherein said light-emitting diodes of the first type are independently switchable from said light-emitting diodes of the first type.
3. A light source according to claim 1 or 2, wherein said first emission spectrum is substantially in the range 370 to 450 nm.
4. A light source according to claim 3, wherein said first emission spectrum is substantially in the range 400 to 430 nm.
5. A light source according to any preceding claim, wherein said second emission spectrum is substantially in the range 620 to 700 nm.
6. Use of a light source according to any preceding claim, in the treatment of a pre-cancerous condition.
7. Use according to claim 6, wherein said pre-cancerous condition is an actinic keratosis.

8. Use of a light source according to any one of claims 1 to 5, for the treatment of a non-melanoma.
- 5 9. Use according to claim 8, wherein said non-melanoma is a basal cell or squamous cell carcinoma.
- 10 10. A light source for therapy and/or diagnosis, comprising a non-planar array of light-emitting diodes conforming with the shape of an external area of a patient to be treated or diagnosed.
11. A light source as claimed in claim 10, wherein said array is mounted on a head portion for attachment to the head of a patient.
- 15 12. A light source as claimed in claim 10, wherein said array is mounted on a flexible support for attachment to the external area.
- 20 13. A light source for therapy and/or diagnosis, comprising a first array of light-emitting diodes and a second array of light emitting diodes movably connected thereto.
- 25 14. A light source as claimed in claim 13, further including a third array of light-emitting diodes movably connected to the first array.
15. A light source as claimed in claim 14, further including a fourth array of light-emitting diodes movably connected to the first array.
16. A light source as claimed in any one of claims 13 to 15, arranged for treatment of the face and/or scalp.

17. A light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on the curved inner surface of a housing arranged to cover at least part of the length of a patient.
- 5 18. A light source as claimed in claim 17, further comprising an array of light-emitting diodes arranged for positioning beneath the patient.
- 10 19. A light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a housing, and an aperture allowing a part of the patient's body to be inserted into the housing, the array being arranged to direct light onto the part of the patient's body when inserted into the housing.
- 15 20. A light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a sleeve so as to direct light onto part of an arm and/or hand of a patient when inserted into the sleeve.
- 20 21. A light source for therapy or diagnosis of a patient, comprising an intraluminal probe carrying on a surface thereof an array of discrete light-emitting diodes.
- 25 22. A light source as claimed in claim 21, wherein said surface is substantially cylindrical.
23. A light source as claimed in claim 21, wherein said surface is substantially spherical.

24. A light source for therapy or diagnosis, comprising an array of light-emitting diodes arranged to give an output intensity of at least approximately 10 mW/cm^2 in a treatment field, and means for cooling the diodes by forced air convection.
- 5
25. A light source as claimed in claim 24, arranged so that light from the light-emitting diodes is incident directly on the treatment field with a spatial intensity fluctuation of approximately 10% or less.
- 10
26. A light source as claimed in claim 24 or 25, wherein the diodes are thermally coupled to one or more heatsinks.
27. A light source as claimed in claim 24, wherein the diodes are mounted at the distal end of a passage for carrying the air from the proximal to the distal end.
- 15
28. A light source as claimed in claim 27, including a fan mounted at the proximal end of the passage.
- 20
29. A light source as claimed in claim 27 or claim 28, wherein the distal end is dimensioned so as to be locatable proximate the cervix of a patient such that light from the diode array is incident on the cervix.
- 25
30. A light source as claimed in claim 29, wherein the distal end is concave so as to fit over the cervix.
31. A light source for therapy or diagnosis, comprising an array of light emitting diodes coupled to light guiding means for delivering light emitted by the diodes to an area to be treated.
- 30

32. A light source as claimed in claim 31, wherein at least part of the light guiding means is tapered away from the diodes.
- 5 33. A light source as claimed in claim 32, wherein the light guiding means includes a tapered part which tapers away from the diodes so as to concentrate the light emitted by the diodes into a parallel-sided light guide.
- 10 34. A light source as claimed in claim 31, wherein the light emitting diodes are integrated in the array.
35. A light source as claimed in claim 34, wherein the diodes are thermally coupled to thermoelectric cooling means.
- 15 36. A light source as claimed in claim 34 or 35, wherein the light guiding means comprises a parallel-sided light guide coupled to the integrated array.
- 20 37. A light source as claimed in claim 33 or 36, wherein the parallel-sided light guide comprises one or more optical fibres and/or liquid light guides.
- 25 38. A light source for therapy or diagnosis, comprising an array of light emitting diodes having emission wavelengths substantially within the range 550 to 660 nm.
- 30 39. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 590 to 640 nm.

40. A light source as claimed in claim 39, wherein the diodes are of aluminium indium gallium phosphide/gallium phosphide die material.
- 5 41. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 560 to 644 nm.
42. A light source as claimed in claim 41, wherein the diodes are of aluminium indium gallium phosphide/gallium arsenic die material.
- 10 43. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 650 to 660 nm.
44. A light source as claimed in claim 43, wherein the diodes are of aluminium gallium arsenic die material.
- 15 45. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 550 to 570 nm.
- 20 46. A light source as claimed in claim 45, wherein the diodes are of gallium phosphide die material.
47. A light source for therapy or diagnosis, comprising an array of LED's with peak emission spectra of approximately 470 nm, 505 nm or 525 nm.
- 25 48. A light source as claimed in claim 47, wherein the diodes are of indium gallium nitride die material.

49. A therapeutic light source comprising an array of LED's with peak emission spectra of approximately 430 nm.
50. A light source as claimed in claim 49, wherein the diodes are of gallium nitride/silicon die material.
51. A light source as claimed in any of claims 10 to 50, wherein said LED's include a first set of LED's and a second set of LED's having different emission spectra from said first set.
52. A light source for therapy or diagnosis, comprising an LED array including a first set of LED's and a second set of LED's having different emission spectra from said first set.
53. A light source as claimed in claim 52, wherein the first and second set of LED's are independently switchable.
54. A light source for therapy or diagnosis, comprising an LED array including a first set of LED's and a second, spatially distinct set of LED's independently switchable from said first set.
55. Use of a light source as claimed in any one of claims 10 to 50 except for claims 29 and 30, and claims dependent thereon, for cosmetic treatment of a patient.
56. Use as claimed in claim 55, for photodynamic treatment of the patient.
57. Use as claimed in claim 56, for portwine stain removal, or hair restoration or removal.

58. Use as claimed in claim 55, for skin rejuvenation, wrinkle removal or biostimulation.
- 5 59. Use of a light source as claimed in any one of claims 10 to 54, for medical treatment of a patient.
60. Use as claimed in claim 59, for photodynamic treatment of a patient.
- 10 61. Use as claimed in claim 60, except when dependent on claim 29 or 30, in the treatment of one or more of actinic/solar keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, eczema, psoriasis, nevus sebaceous, gastrointestinal conditions (e.g. Barratt's oesophagus and colorectal carcinomas), gynaecological disorders (e.g. VIN, CIN and excessive uterine bleeding), oral cancers (e.g. pre-malignant or dysplastic lesions and squamous cell carcinomas),
- 15 viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata, or hirsutism.
- 20 62. A light source for therapy or diagnosis substantially as herein described with reference to and/or as shown in Figures 1 to 4, or Figure 5, or Figure 6, or Figure 7, or Figure 8, or Figure 9, or Figures 10a and 10b, or Figures 11a to 11c, or Figure 12, or Figure 13, or Figure 14, or Figure 15, or Figures 16a and 16b, or Figures 17a and 17b, or Figures 18a and 18b, or Figures 19a and 19b, or
- 25 Figures 20a and 20b, or Figure 21, or Figures 22a to 22c, or
- 30

Figures 23a to 23c, or Figure 24, or Figure 25, or Figure 26 of the accompanying drawings.



INVESTOR IN PEOPLE

Application No: GB 0030974.0

Examiner: Susan Chalmers
(Mrs)

Claims searched: 1-10

Date of search: 24 May 2001

Patents Act 1977
Search Report under Section 17**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): A5R: REHR

Int Cl (Ed.7): A61N: 5/06

Other: ONLINE: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
E,X	WO 01/14012 A (RUSSELL) see Figures, page 5 line 24 to page 6 line 9, page 21 line 20 to page 22 line 29 and page 24 line 1 to page 25 line 12	1,2 at least
P,Y	WO 00/15296 A (LIGHT SCIENCES) see eg Figures 5-8, page 2 line 31 to page 3 line 9 and page 8 line 3 to page 10 line 6	1-9
X	WO 99/19024 A (VIRULITE) see Figures 13 and 14 and page 8 lines 15-20	1,2 at least
X	WO 98/43703 A (PRESCOTT) see especially page 5 lines 16-26, page 9 lines 16-26 and page 18 lines 4-25	1,2 at least
Y	EP 0266038 A (KUREHA) see photodiodes 3a,3b in Figures 1-3 and page 3 lines 32-40	1,3-5
X	US 5616140 (PRESCOTT) see parts 20,22,702,802 in the Figures, column 5 lines 1-10 and 54-62 and column 14 line 64 to page 15 line 9	1,2,5-9 at least

X Document indicating lack of novelty or inventive step
Y Document indicating lack of inventive step if combined with one or more other documents of same category.

& Member of the same patent family

A Document indicating technological background and/or state of the art.
P Document published on or after the declared priority date but before the filing date of this invention.

E Patent document published on or after, but with priority date earlier than, the filing date of this application.

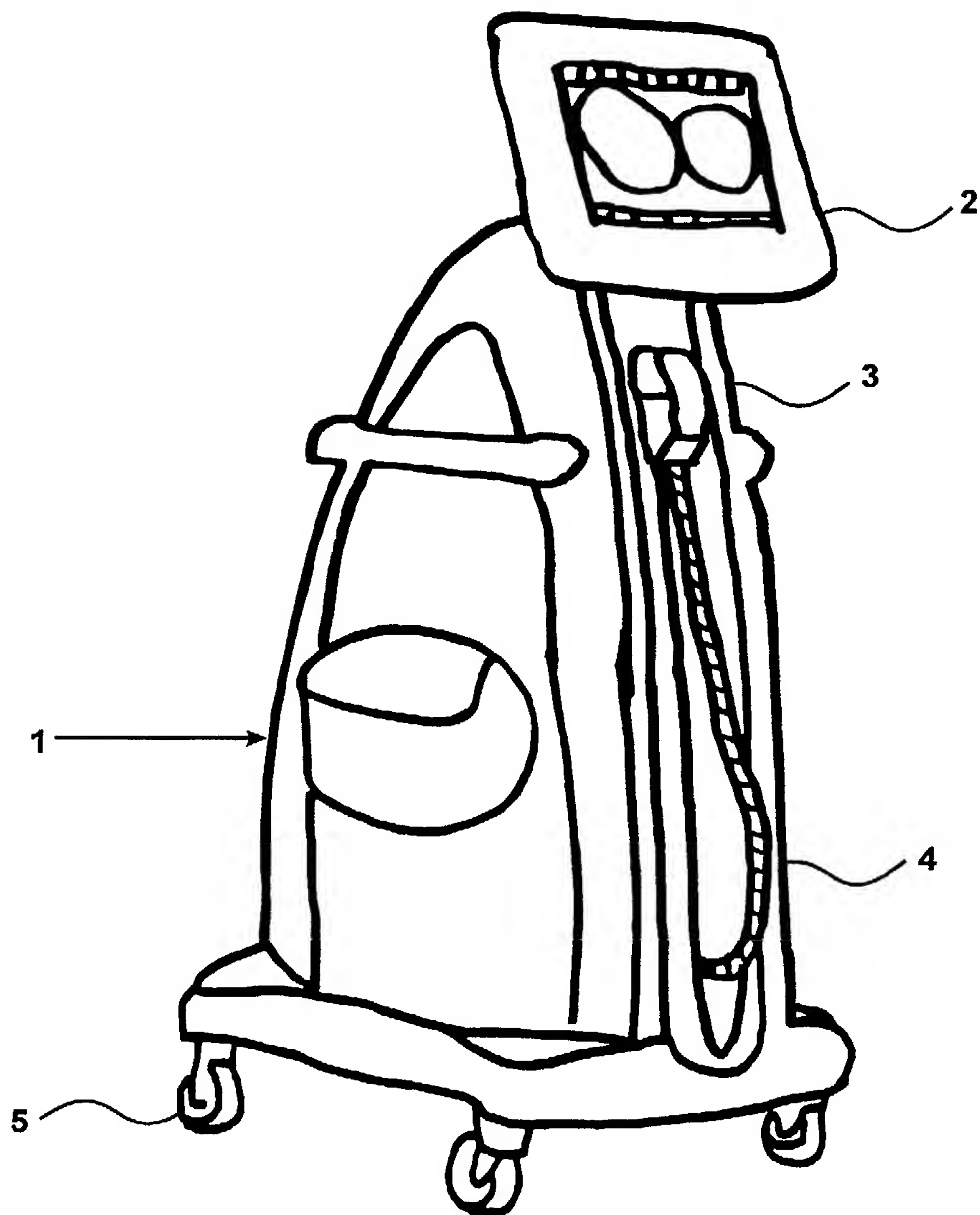


Figure A

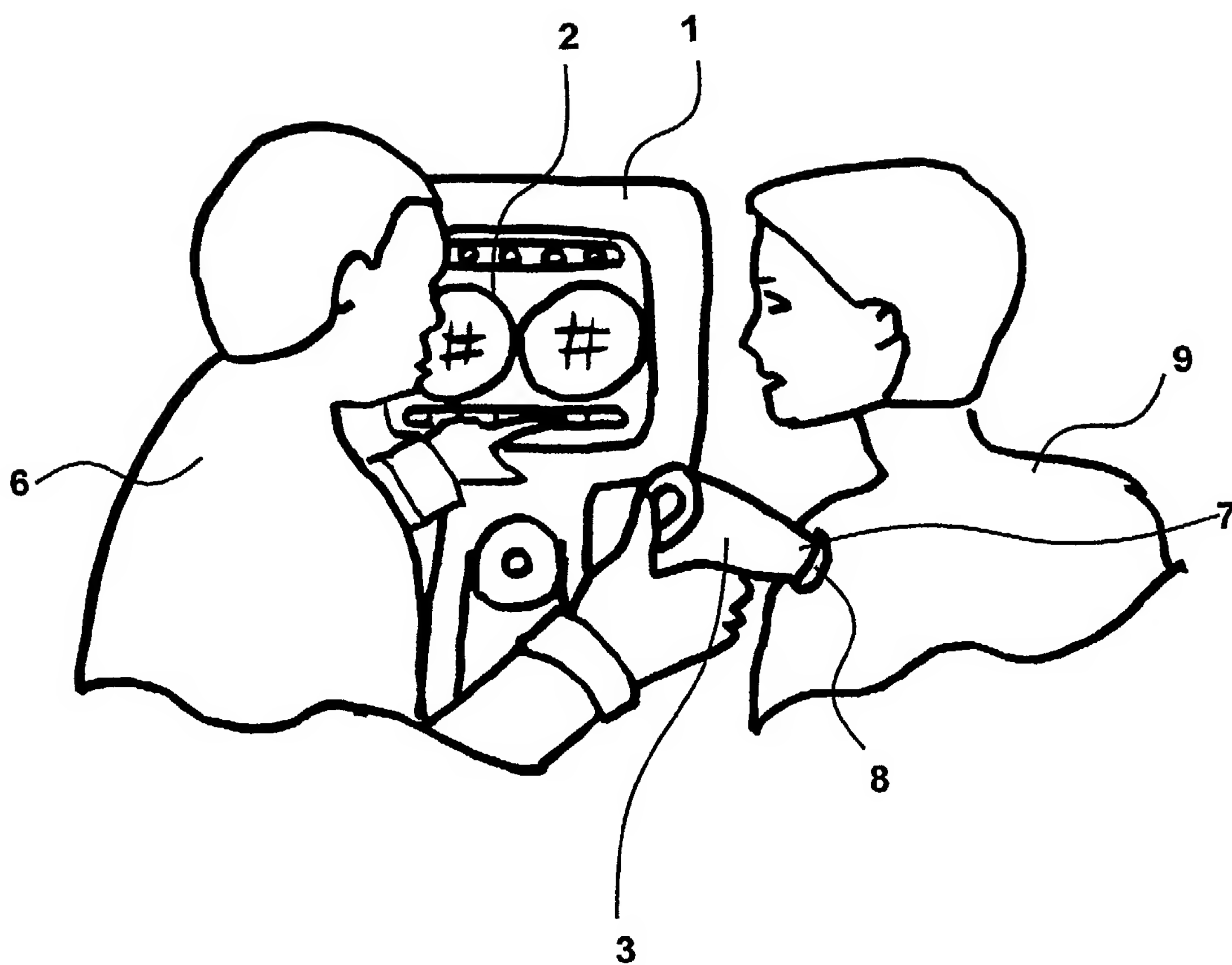


Figure B

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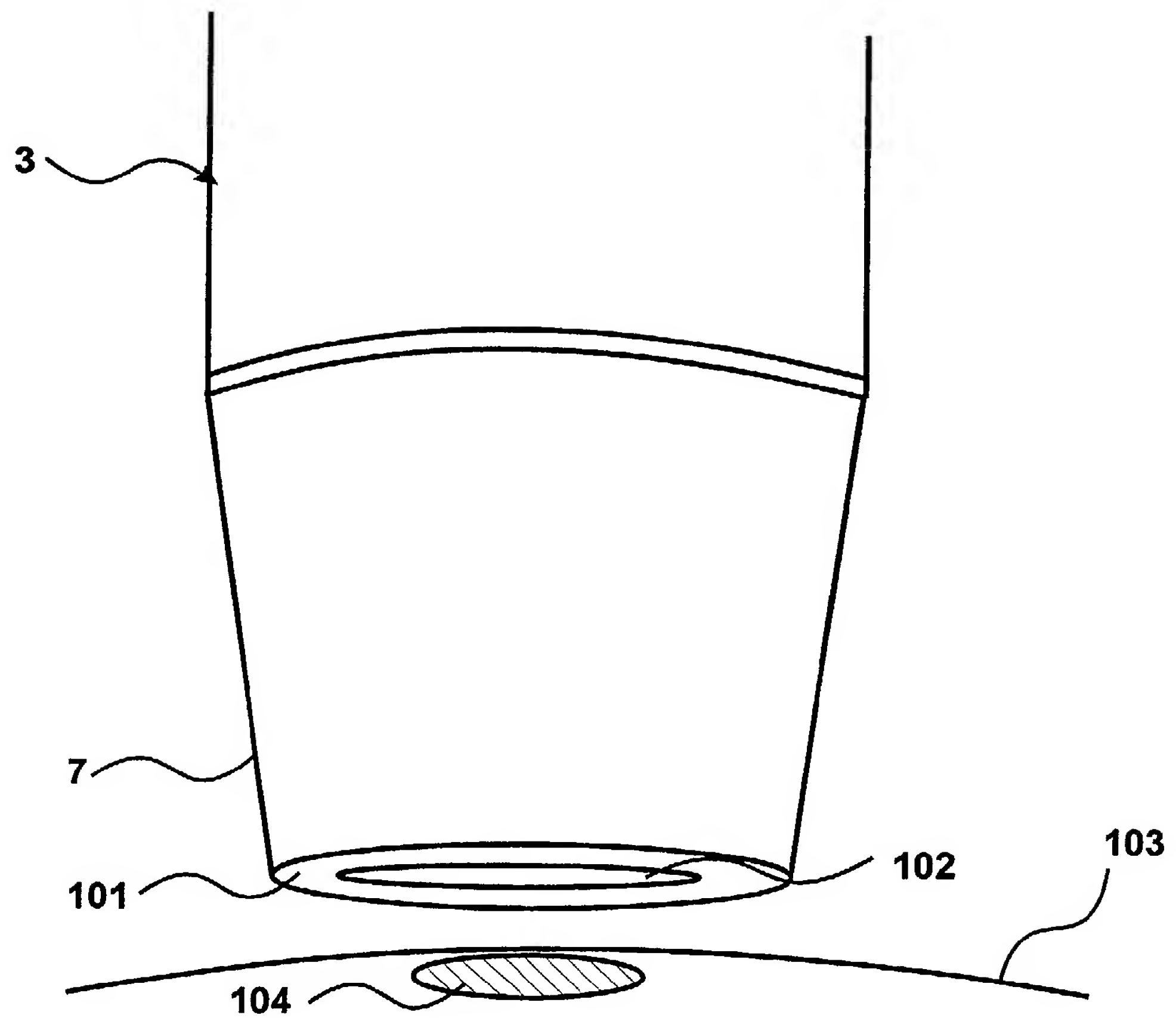


Figure 1

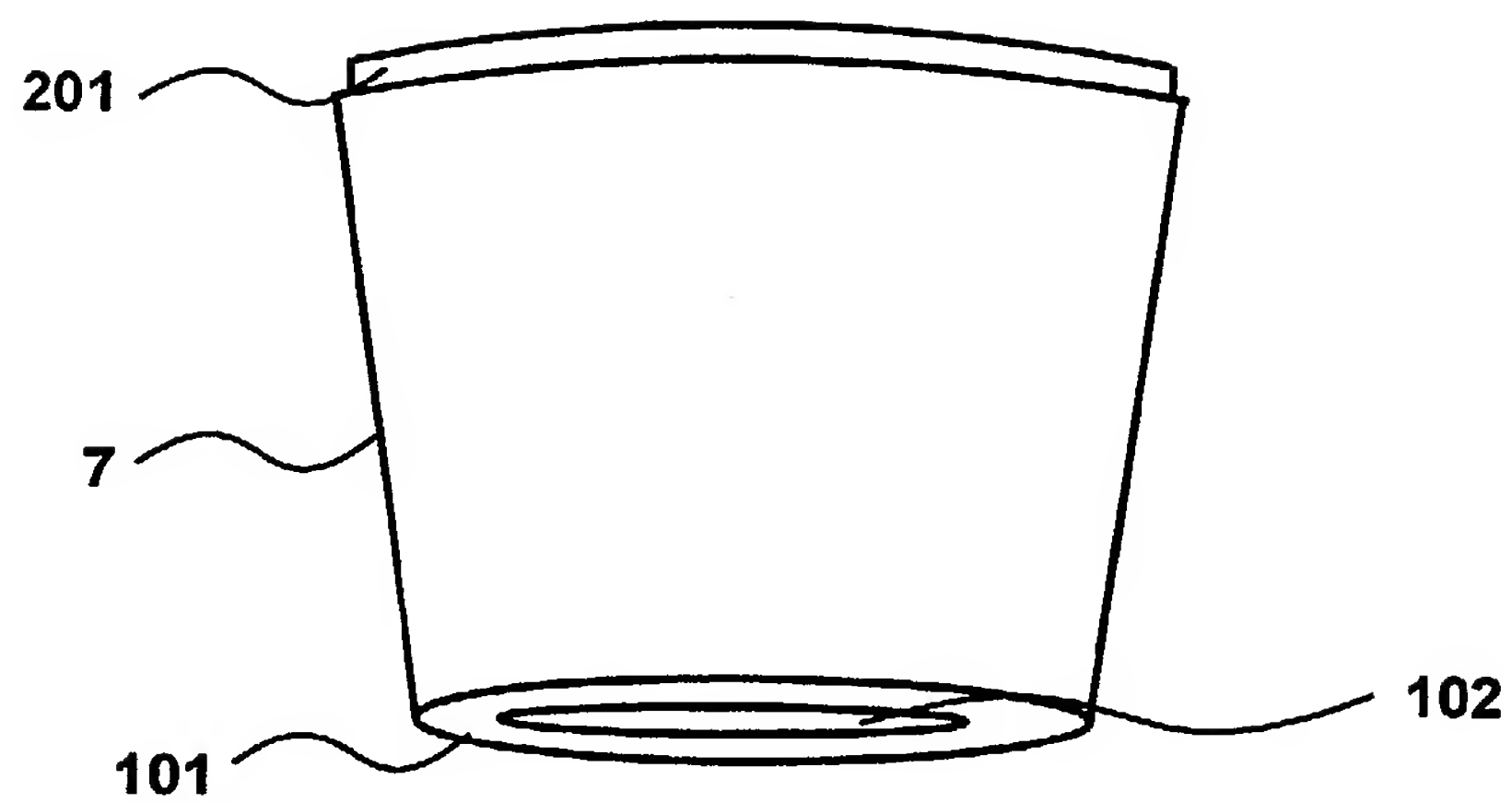


Figure 2a

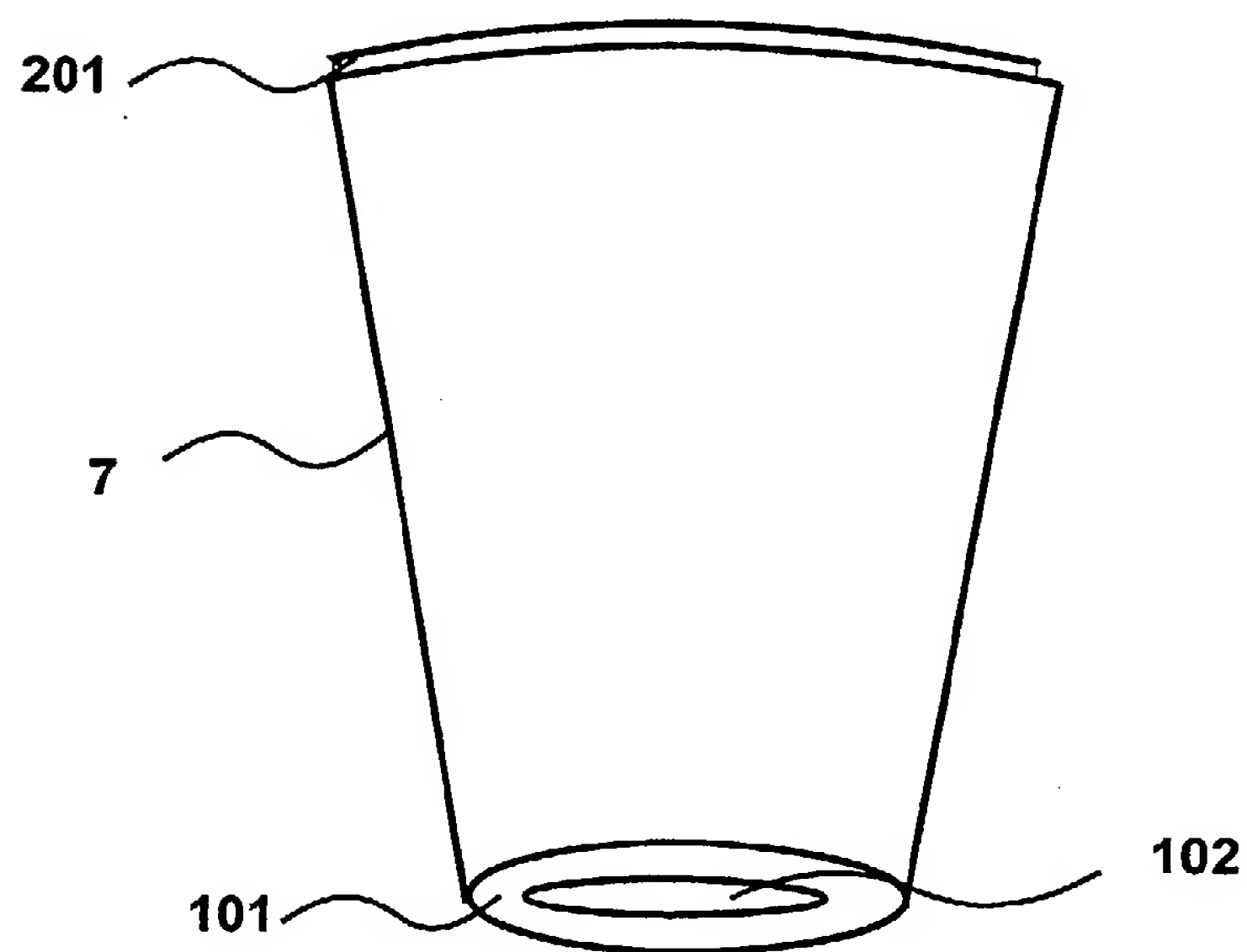


Figure 2b

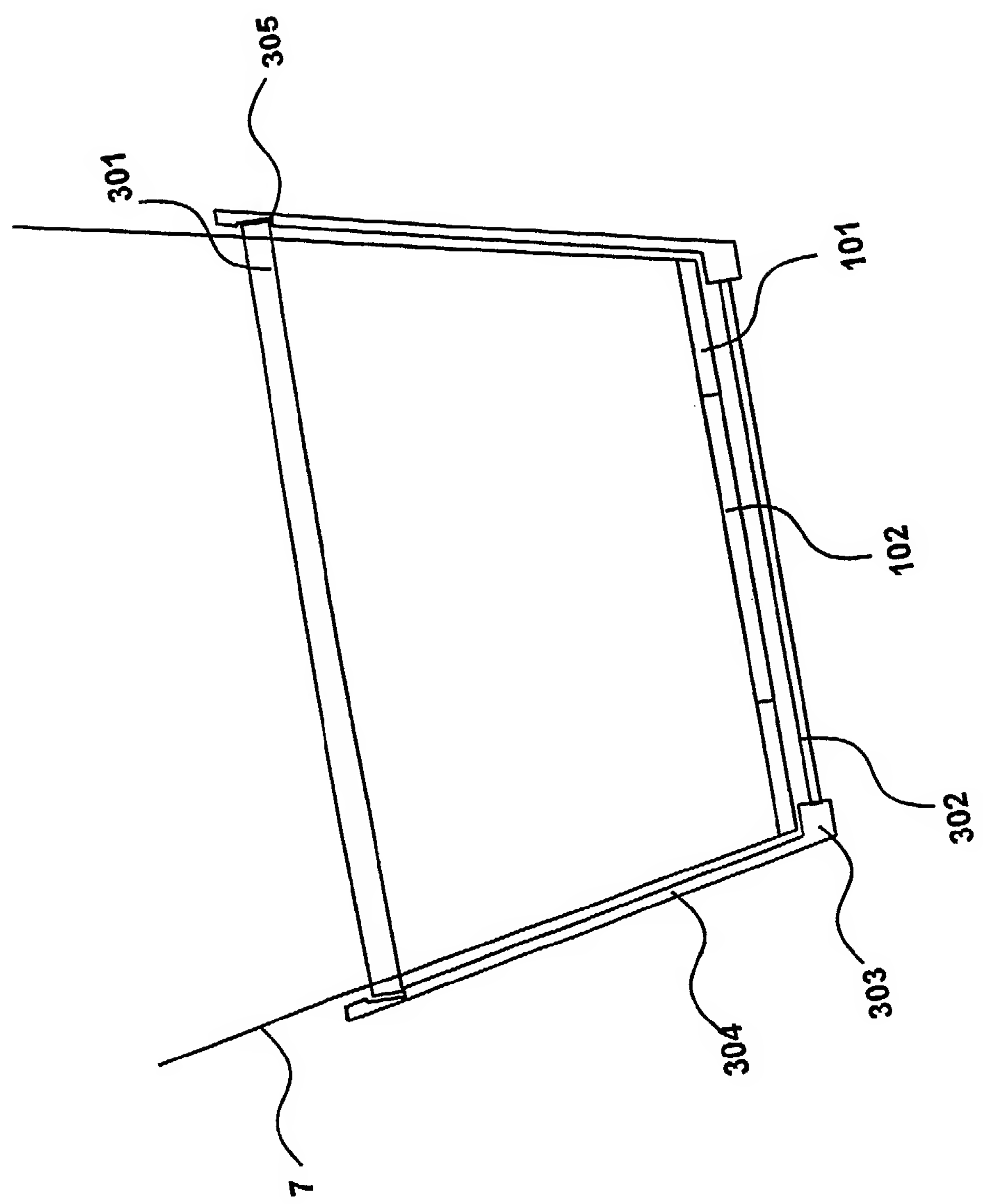


Figure 3

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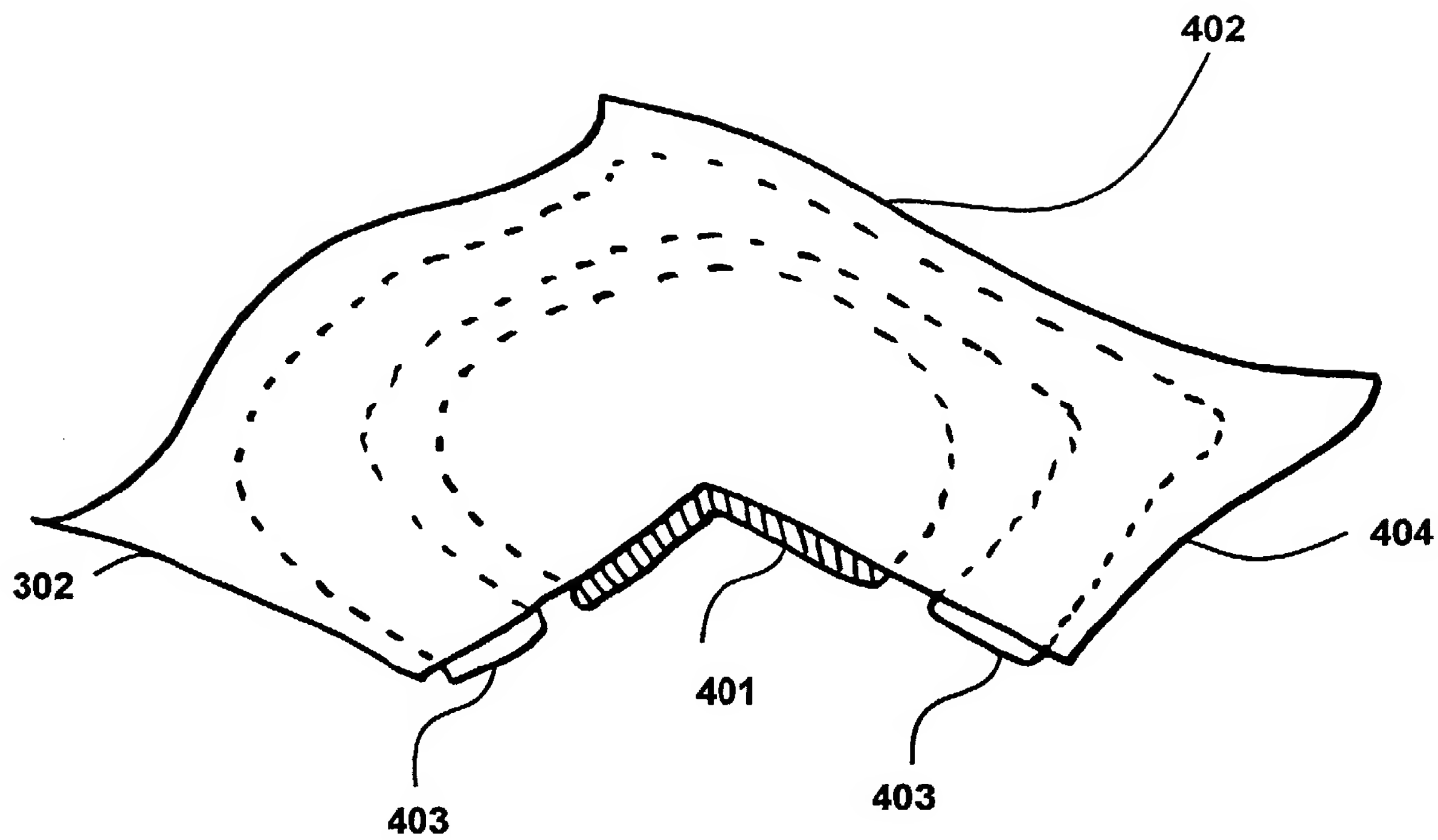


Figure 4

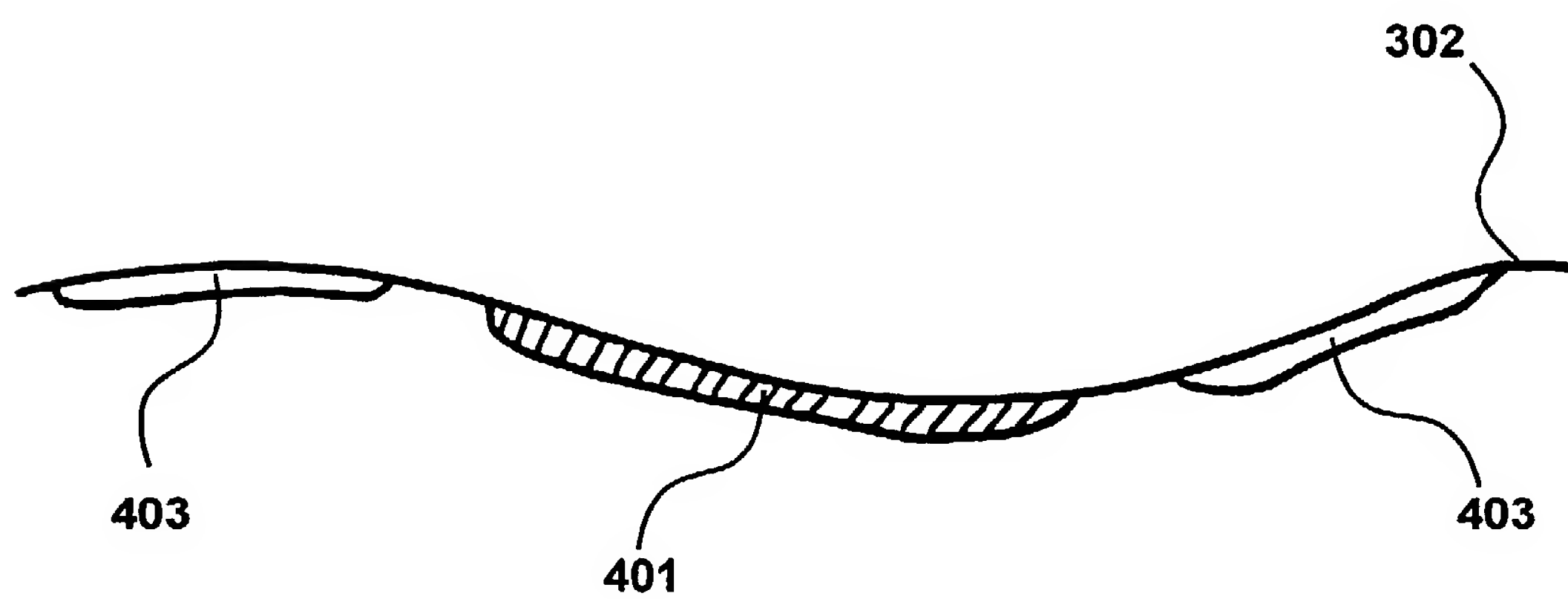


Figure 5

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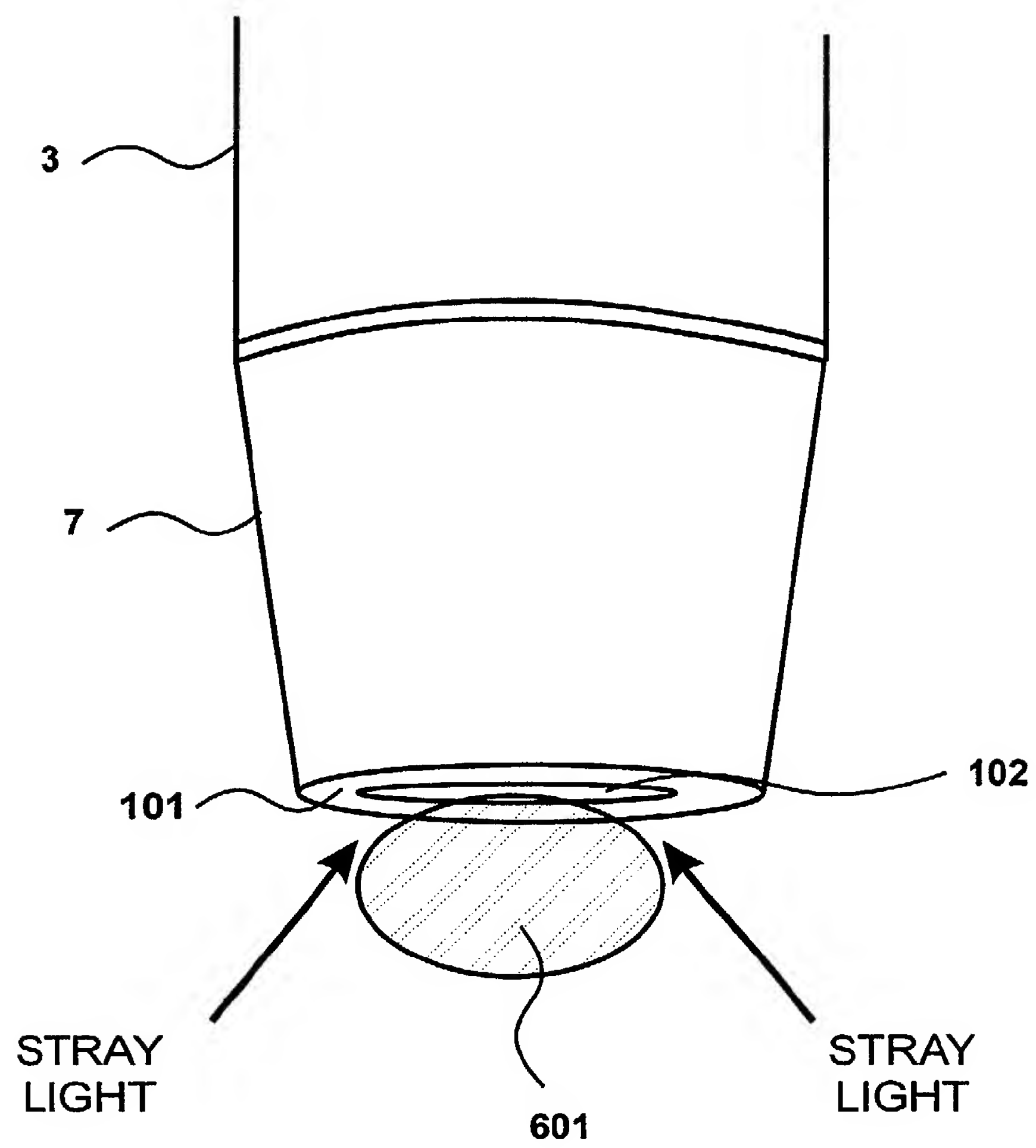


Figure 6

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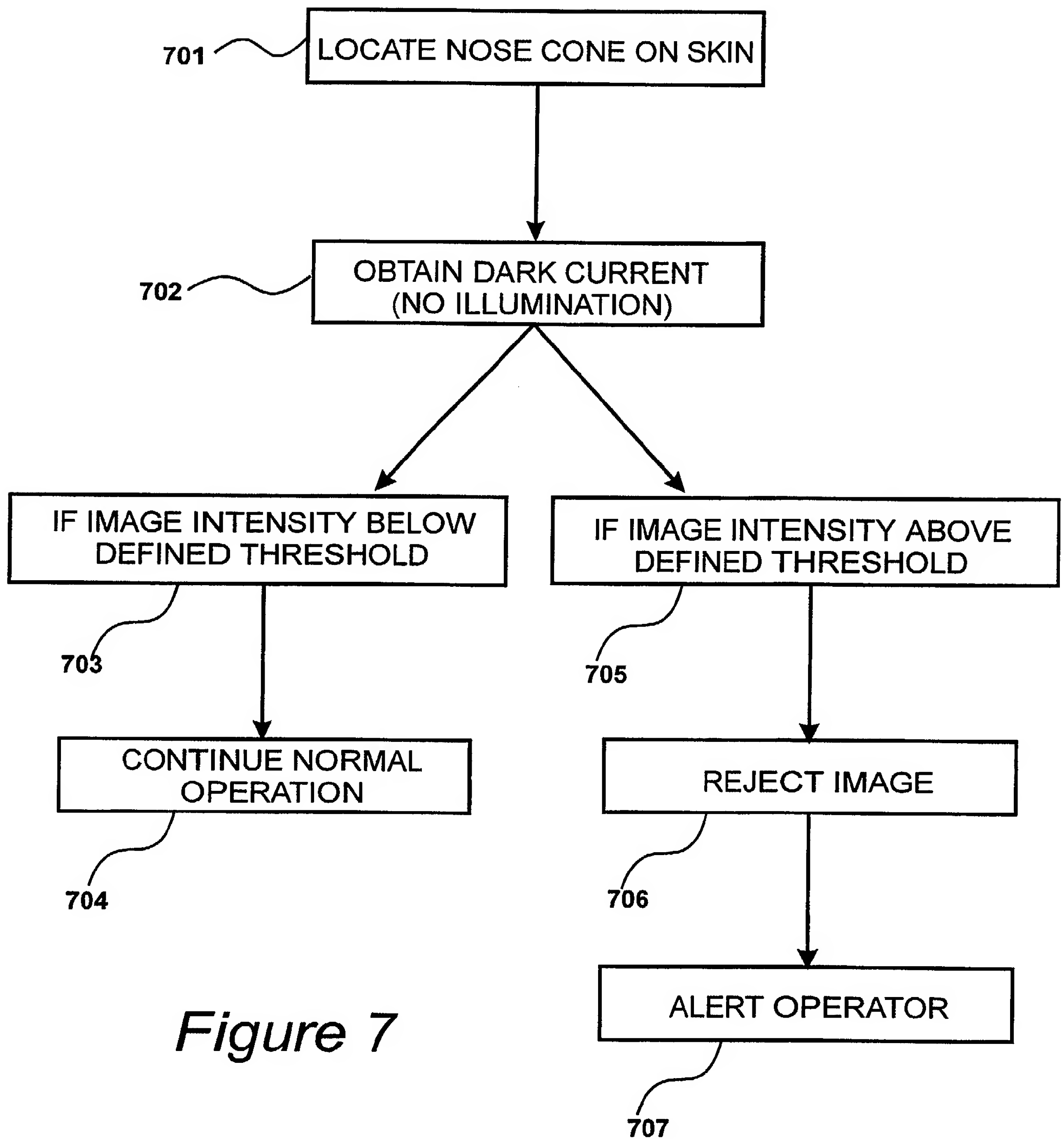


Figure 7

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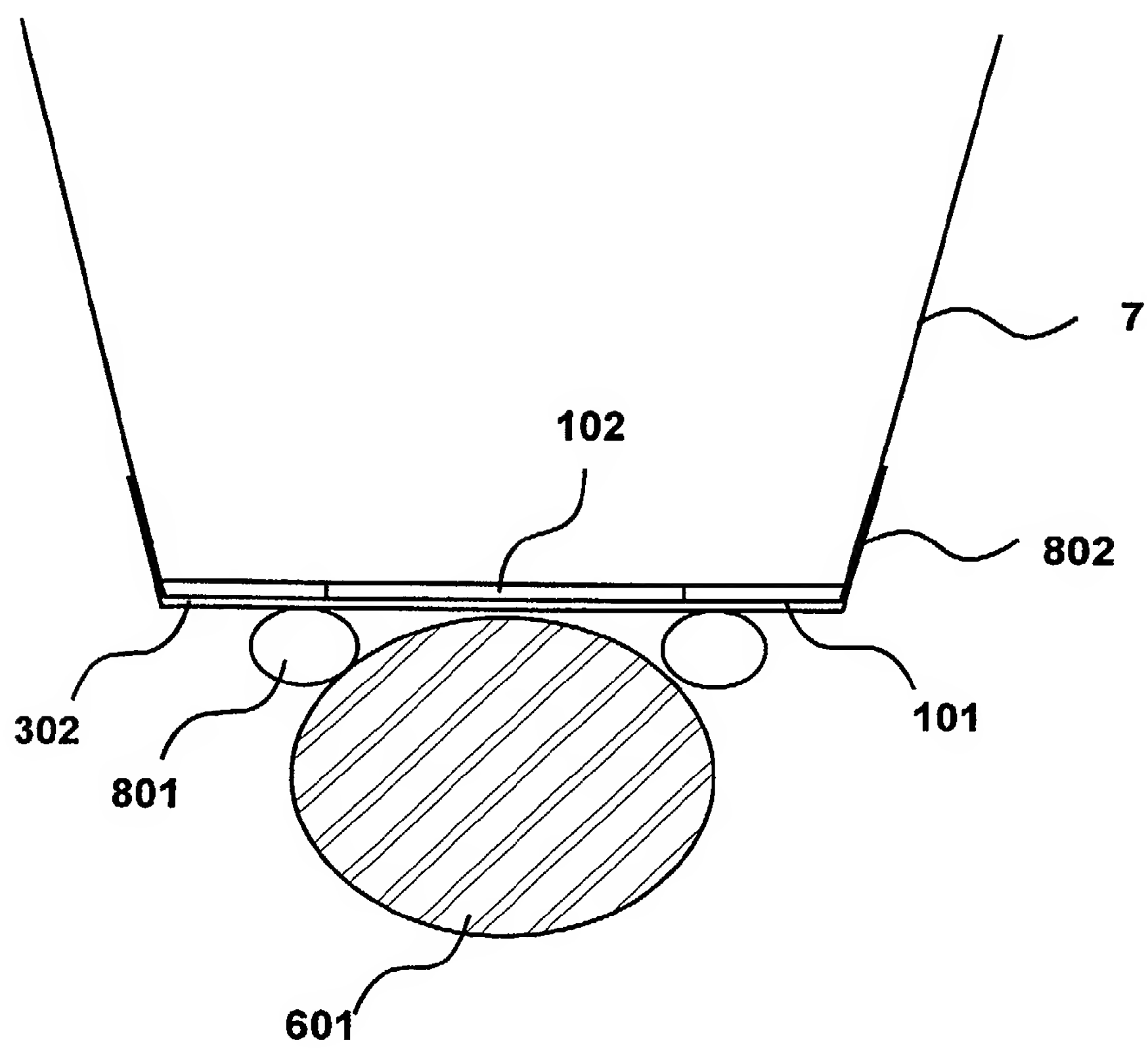


Figure 8

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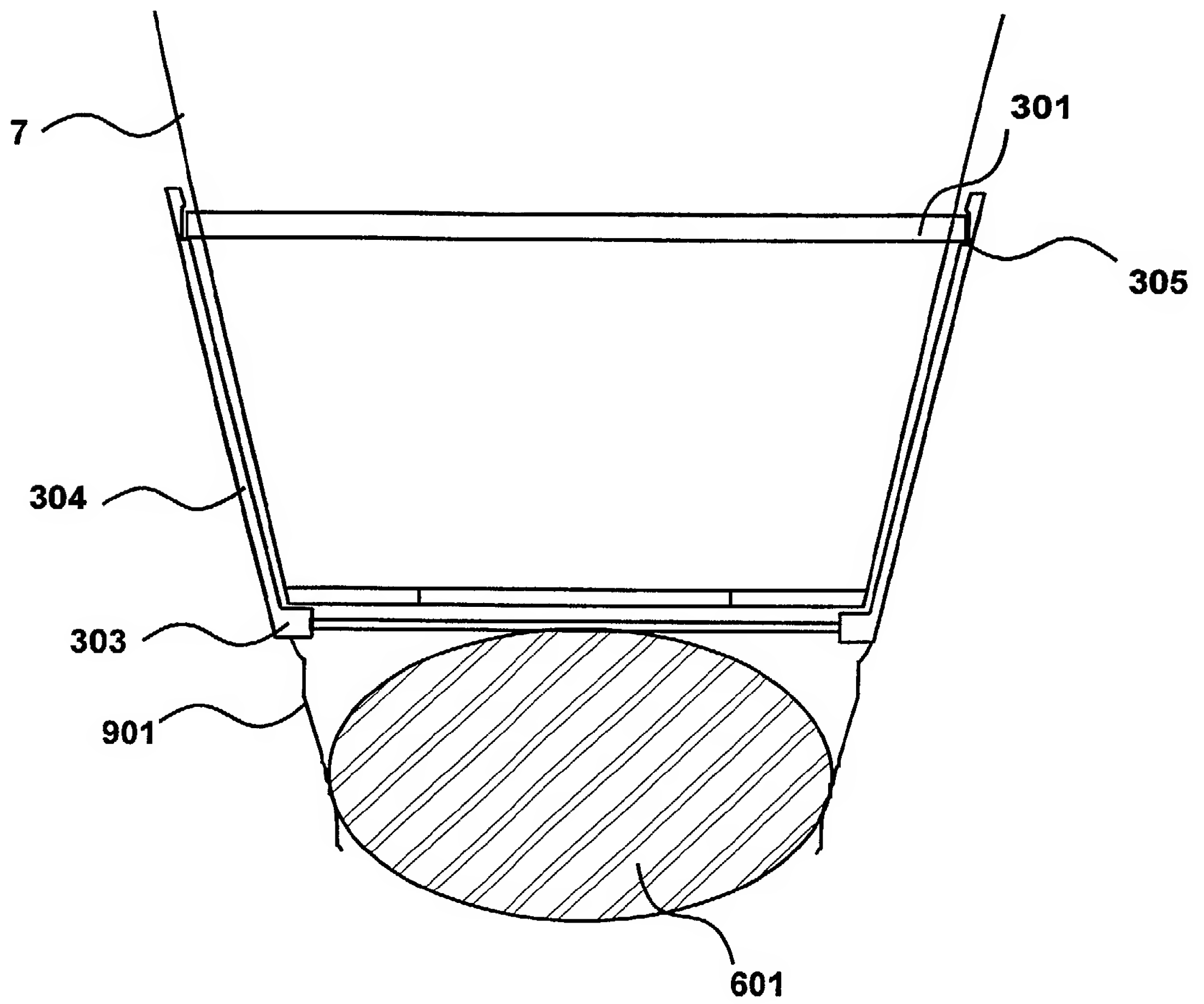


Figure 9

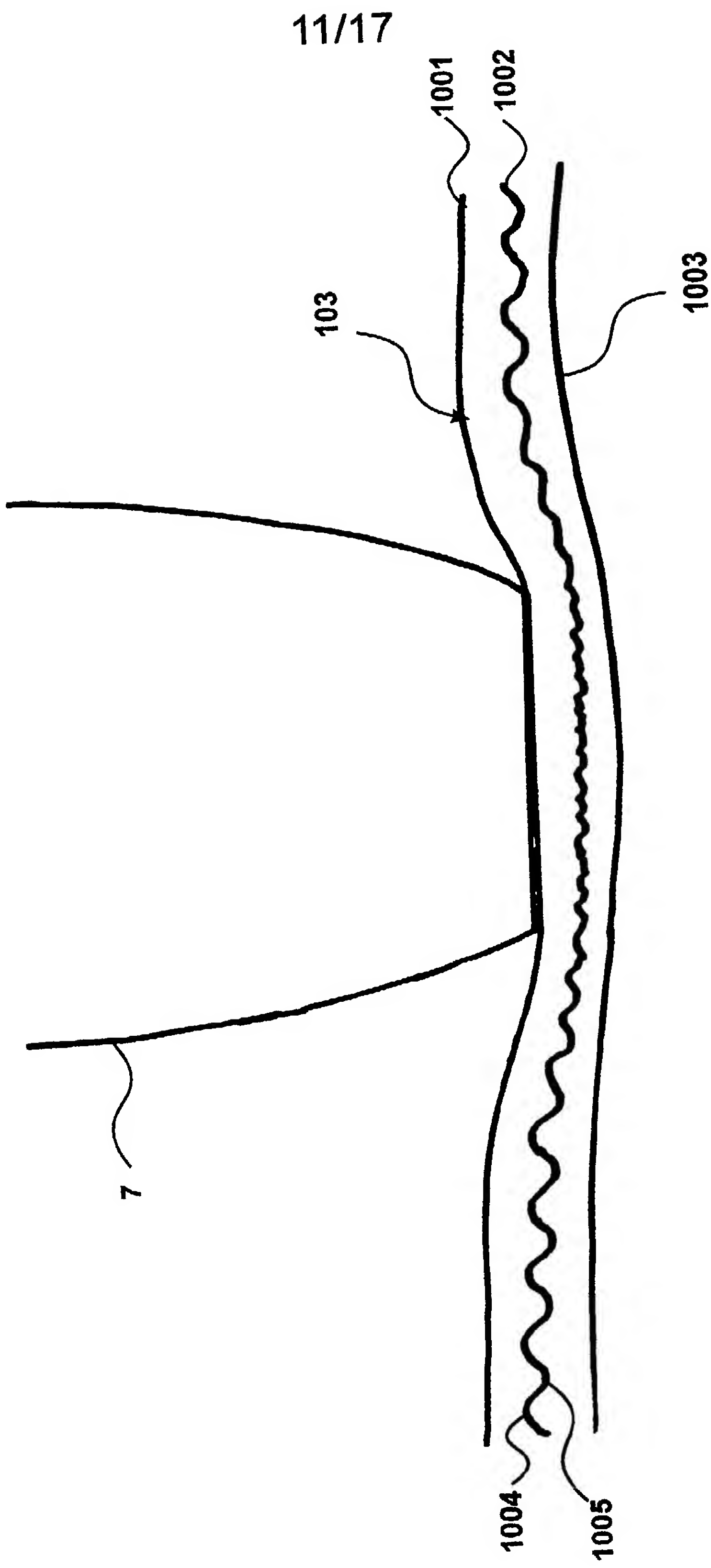


Figure 10

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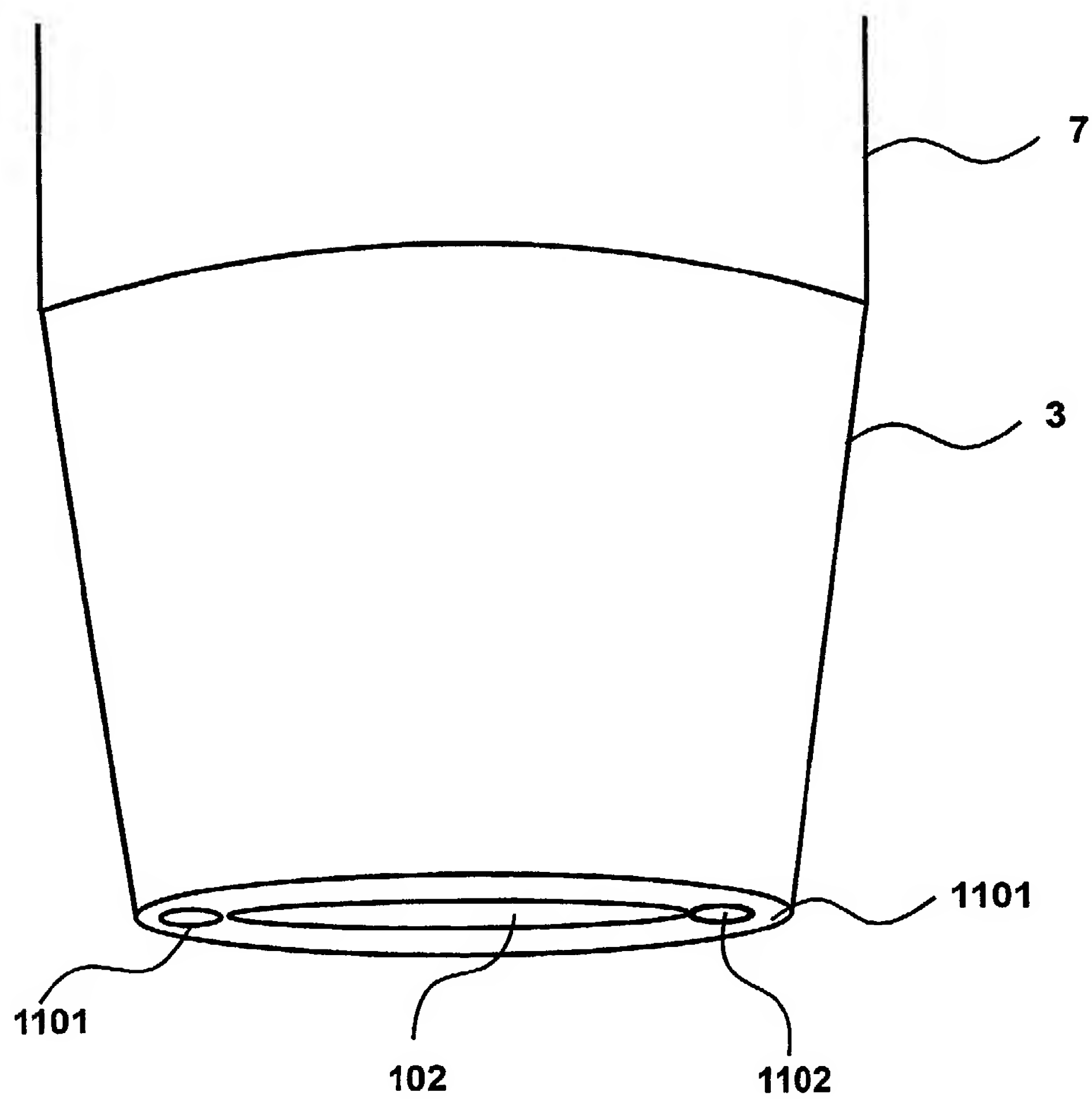


Figure 11

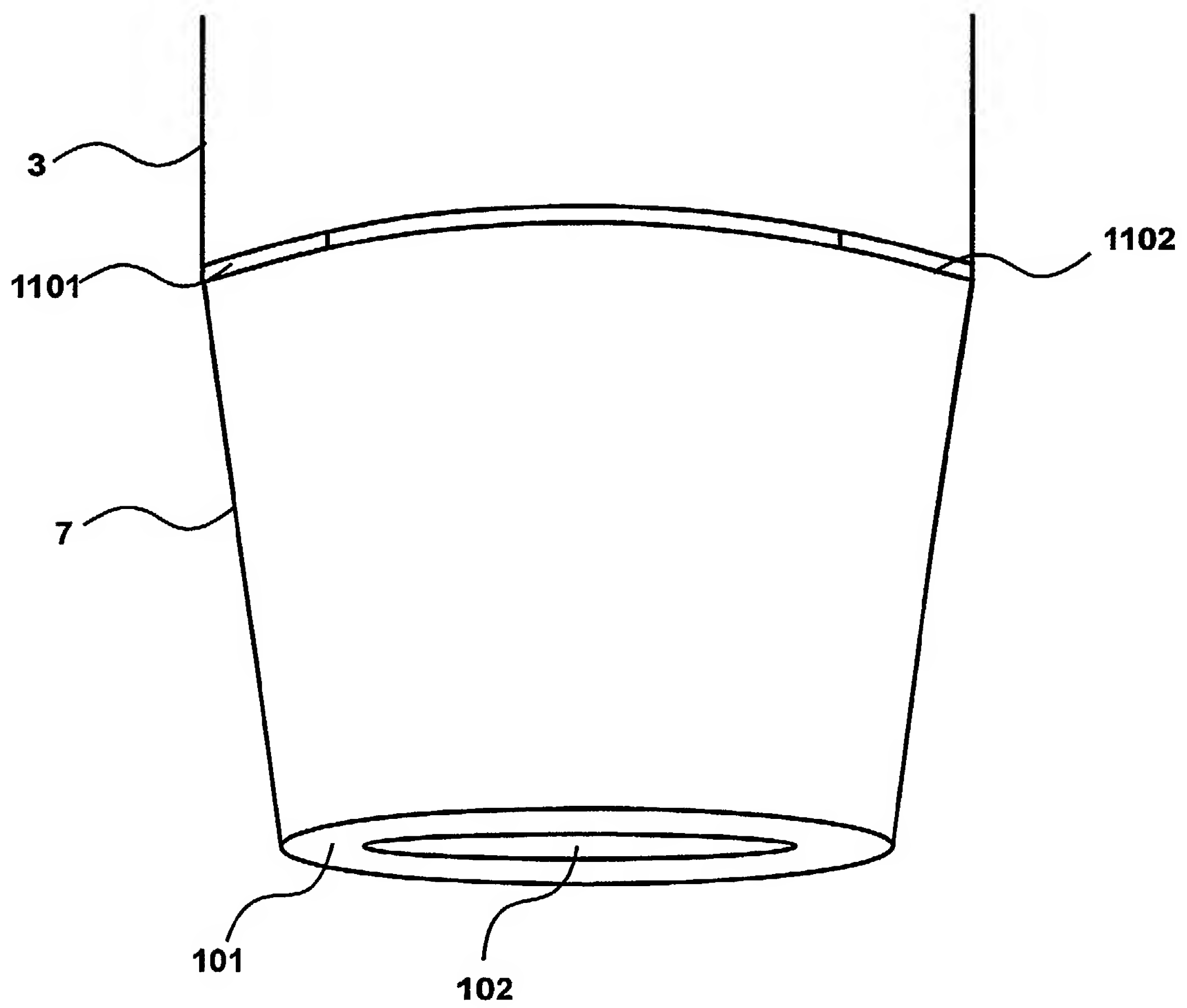


Figure 12

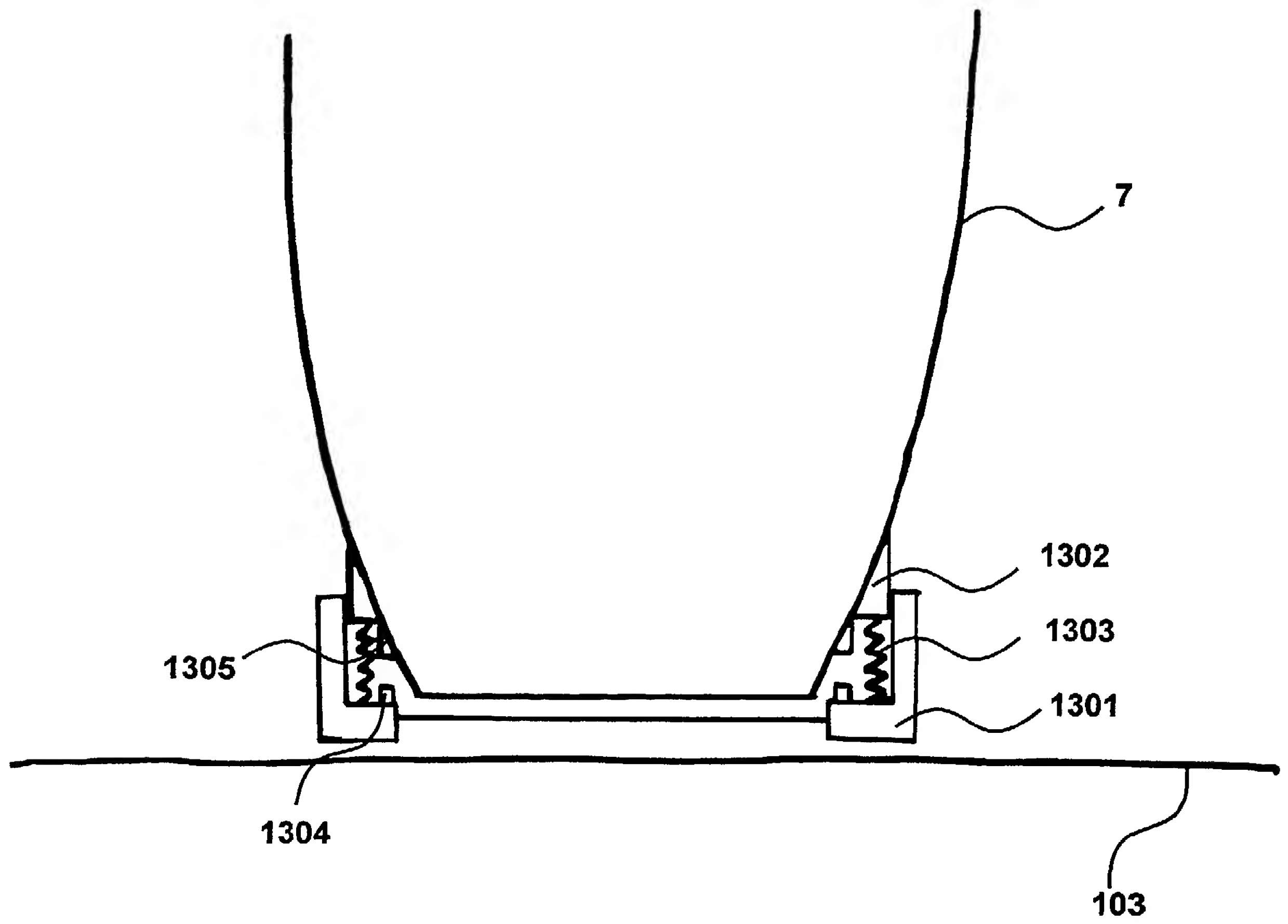
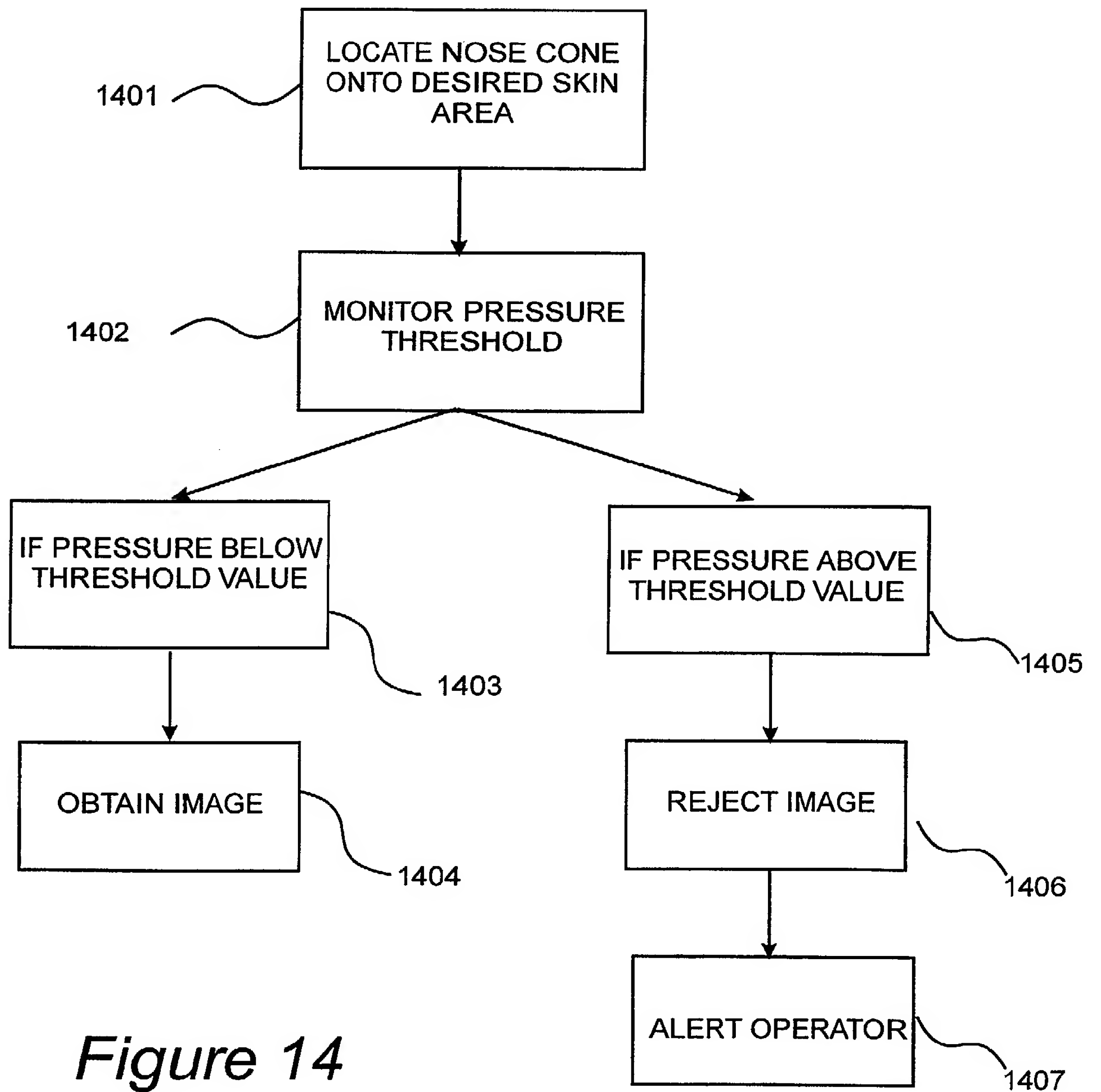


Figure 13

*Figure 14*

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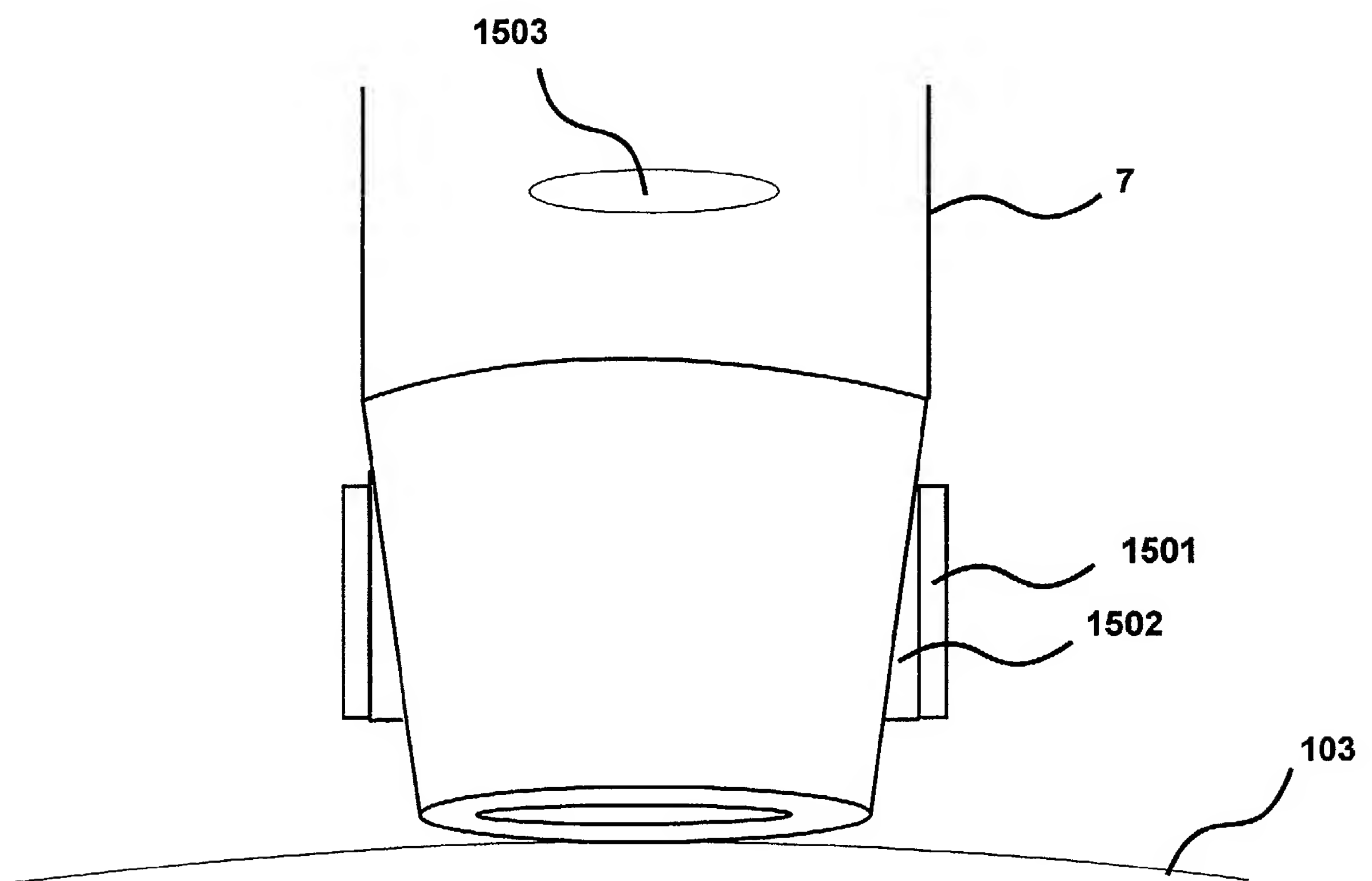


Figure 15

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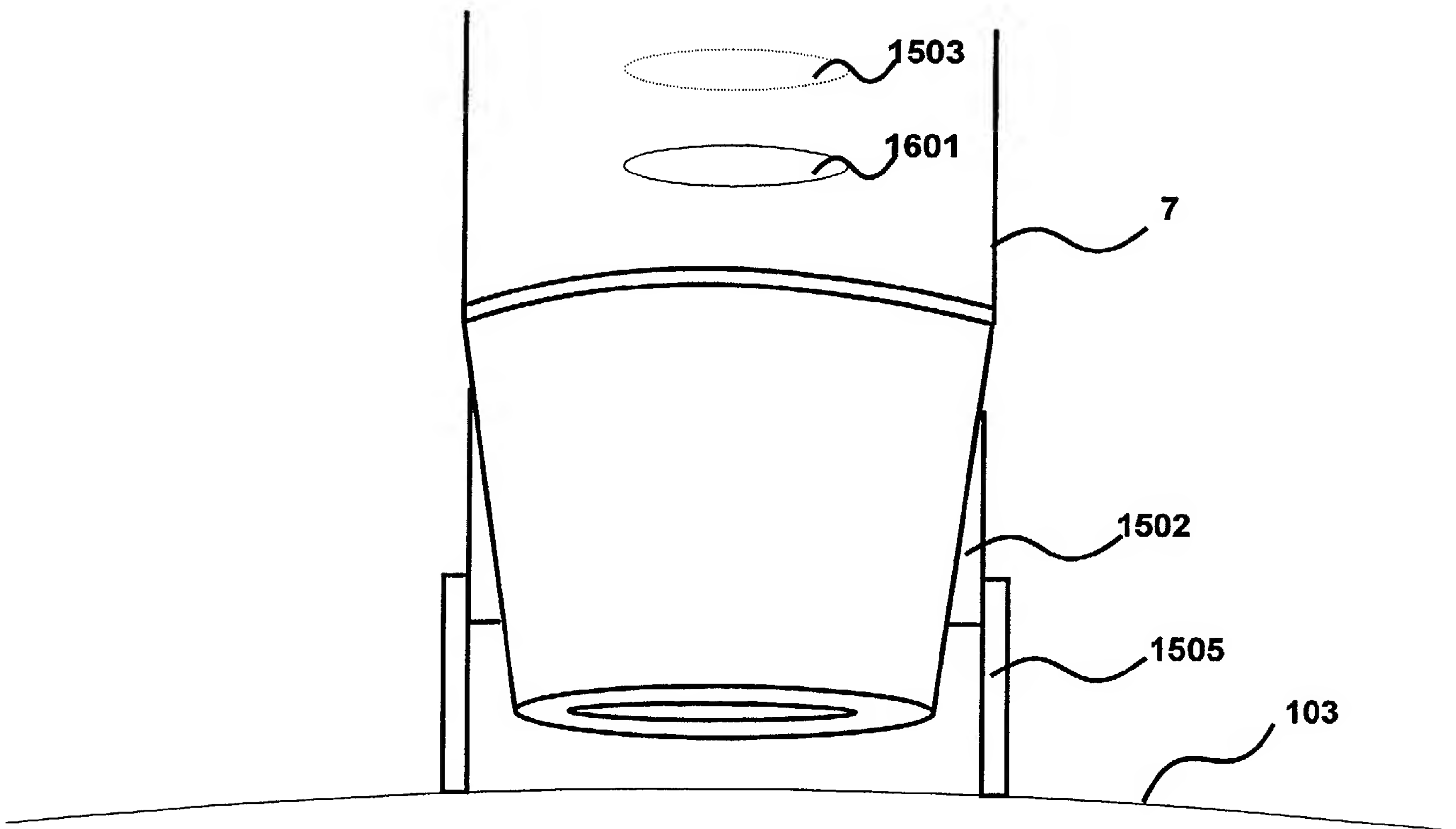


Figure 16

Skin Diagnostic Aid

Field of the invention

5 The present invention relates to a skin diagnostic aid and more particularly to a nose cone for use with skin illumination and remitted light detection apparatus as described in UK Patent Application Number 00 10 888.6.

Background to the invention

10 Conventional methods for the diagnosis of skin ailments involve the examination of the surface characteristics of a skin lesion. In addition, and dependant on the skin condition, a proportion or entire area of a skin lesion may be surgical excised and used for histological examination under a microscope.

15 There are a variety of skin conditions where the provision of histological information rapidly would be a valuable adjunct to enable the efficient diagnosis of a skin ailment. In the example of a malignant melanoma, histological information could be vital to determining the prognosis of the disease. For instance, the ingression of melanocytes into the papillary dermis and in particular the depth of ingression has been correlated to the prognosis
20 of the disease (Neville, C.D. "Melanoma: Issues of Importance to the clinician", British Journal of Hospital Medicine, 1995). For this reason, a device which could provide histological information about an area of skin rapidly and by a non-invasive technique would be a distinct advantage.

25 The principal chromophores located in the skin include melanin, haemoglobin, oxy-haemoglobin and collagen. In normal healthy skin, melanin is located exclusively in the epidermis, and haemoglobin and oxy-

haemoglobin are located primarily in the papillary dermis and to a lesser extent the reticular dermis. Collagen is located throughout the dermis, with the highest concentration residing in the reticular dermis. Abnormalities in the distribution of such chromophores can provide valuable information about the histology of a skin ailment and can be obtained by detecting and interpreting the distribution of different chromophores within the skin.

Our co-pending United Kingdom patent application numbers 99 12 908 and 99 25 414 relate to advances and improvements in the determination of the concentration and distribution of chromophores within the skin. In particular, United Kingdom patent application number 99 12 908 relates to methods and apparatus by which the histology of the skin may be determined and the identification of the presence depth and concentration of chromophores within the skin. United Kingdom patent application number 99 25 414 relates to a method and apparatus for providing the information of the skin structure, more particularly, to mapping the surface of dermal papillae.

Furthermore, our co-pending United Kingdom Patent Application Number 00 10 888.6 relates to an apparatus and methodology for determining the distribution of chromophores within the histological layers of the skin. An example of the skin illumination and remitted light detection apparatus to which the present invention relates is illustrated in *Figure A*. The skin illumination and remitted light detection apparatus has a housing 1 onto which is mounted a display screen 2 with a touch screen operation. A handset 3 is stored on the housing 1 when not in use. The handset 3 is connected to the internal system of the equipment by a flexible metal tubing 4 which contains a bundle of optical fibres, which transmit light from a source contained within the housing 1, and carries signals from a detector to a computer located within the housing 1. The apparatus is supported by

castors 5, which enable the equipment of the invention to be conveniently moved into a required location.

5 In use an operator 6 removes the handset 3 from its stored position in the housing 1 and holds the free end 7 of the handset 3 against the target area 8 of the skin of a patient 9, as shown in *Figure B*. The operator 6 may then select options from the touch-screen 2 to initiate the illumination and imaging of the skin area.

10 The images obtained are displayed in a variety of formats on the display screen and the operator 6 can select specific representations and view the presence of specific chromophore constituents of the skin by selecting options from the display screen 2. The images are interpreted by a suitably trained operator and differences in the distribution of chromophores between the image obtained and the predetermined models of normal healthy skin can be visualised.

15 Following the imaging of the skin, the light tube 3 is replaced within the housing and a printout of the images obtained for recording purposes.

It has been found that there are four distinct problems associated with the handset 3 and more particularly with the nose cone, which are detailed below.

20 Problem 1

It is clearly visible in *Figure B* that the nose cone is contacted directly onto the skin surface. It is during this procedure that the nose cone may be come contaminated with material associated with skin surface. The current approach to remove such material is to wipe the glass surface with an
25 alcoholic wipe. However, such a procedure may not result in complete removal contaminants from the skin surface or the glass aperture.

Problem 2

In addition, when the nose cone is located adjacent to areas of skin, such as a finger or nose, where the skin surface is not a smooth flat surface, ambient light or stray light from the surroundings may access the detector and give rise to errors in the measurement of remitted light.

5 Problem 3

A further disadvantage of the current nose cone is the absence of a mechanism for controlling the pressure by which the nose cone is applied to the skin surface. This is particularly significant in, for example, situations where the apparatus is used for mapping the topology of the dermal papillae and applying too much pressure to the skin results in a flattening of these papillae.

10 Problem 4

A final disadvantage of the current nose cone is the requirement to provide a clinician with a clinical view. By clinical view we mean a view of the macroscopic skin surface which is a valuable adjunct to the images of light remitted from an area of skin for which the apparatus to which the present invention pertains is designed.

The present invention is concerned with overcoming the above mentioned problems or at least significantly reducing them.

20 According to the present invention there is provided a skin illumination and remitted light detection apparatus, comprising a light tube defining a transparent glass aperture contactable with the skin, illumination means configured to transmit light to said light tube, detection means to detect light remitted from the skin, wavelength selection means to select the wavelength
25 of light incident on said detection means, and illumination intensity selection means to select the intensity of light incident on the detection means, characterised in that said apparatus further comprises barrier means

configured to prevent direct contact between said glass aperture and said skin.

According to a second aspect of the present invention there is provided a skin illumination and remitted light detection apparatus, comprising a light tube defining a transparent glass aperture contactable with the skin, illumination means configured to transmit light to said light tube, detection means to detect light remitted from the skin, wavelength selection means to select the wavelength of light incident on said detection means, and illumination intensity selection means to select the intensity of light incident on the detection means, characterised in that said apparatus further comprises an ambient light exclusion means to prevent ambient light accessing said glass aperture.

According to a third aspect of the present invention there is provided a skin illumination and remitted light detection apparatus, comprising a light tube defining a transparent glass aperture contactable with the skin, illumination means configured to transmit light to said light tube, detection means to detect light remitted from the skin, wavelength selection means to select the wavelength of light incident on said detection means, and illumination intensity selection means to select the intensity of light incident on the detection means, characterised in that said apparatus further comprises a pressure detection means configured detect a threshold level of pressure between said light tube and the skin.

According to a fourth aspect of the present invention there is provided a skin illumination and remitted light detection apparatus, comprising a light tube defining a transparent glass aperture contactable with the skin, illumination means configured to transmit light to said light tube, detection means to detect light remitted from the skin, wavelength selection means to

select the wavelength of light incident on said detection means, and illumination intensity selection means to select the intensity of light incident on the detection means, characterised in that said apparatus further comprises a means for locating said glass aperture a defined distance from said skin surface such that a clinical view of the skin surface is obtained.

Brief Description of the Several Views of the Drawings

How the invention may be carried out will now be described, by way of example only, with reference to the accompanying drawings, in which:

10 *Figure A* is a perspective view of an example of the equipment to which the present invention relates;

Figure B is a schematic representation of the apparatus of *Figure 1* in use;

15 *Figure 1* is a perspective representation of the nose cone of the apparatus shown in *Figures A* and *B*;

Figure 2a and 2b are perspective representations of an example of disposable nose cones;

Figures 3 is a schematic representation of a nose cone fitted with a disposable film cover;

20 *Figure 4* is a schematic representation of a transparent film coating that may be applied to the skin;

Figure 5 is a cross-sectional view of the film shown in *Figure 6*, taken along the line X-X';

25 *Figure 6* is a schematic representation of a nose cone in contact with a finger;

Figure 7 is a flow chart illustrating an example of an operational sequence to detect the presence of stray light;

Figure 8 is a schematic representation of a film cover attachment;

Figure 9 is a schematic representation of an alternative film attachment shown in *Figure 8*;

5 *Figure 10* is a schematic representation of a nose cone in contact with a skin surface;

Figure 11 is a schematic representation of a nose cone configured to detect the pressure applied to the skin;

Figure 12 is a schematic representation of an alternative embodiment of the nose cone shown in *Figure 11*;

10 *Figure 13* is a schematic representation of a further nose cone equipped with a mechanical means for determining the pressure with which the nose cone is applied to the skin;

Figure 14 is a flow chart showing an example of an operational sequence configured to prevent over pressurising the skin below;

15 *Figure 15* is a perspective view of a nose cone with spacer legs in an upright position; and

Figure 16 is a perspective view of a nose cone shown in *Figure 15* with the legs in a down position.

20 In the drawings the same reference numerals are used for like or corresponding parts in each of the Figures.

Best Mode for Carrying Out the Invention

25 Figure 1 shows a schematic representation of a light pipe 3 having a nose cone 7 with a transparent glass aperture 102 defined by the nose cone ending 101. Illumination from the source, is transmitted from a source located within the housing 1 to the light pipe 3 (see *Figures A and B*) and illuminates the skin 103 through the transparent glass aperture 102. Also shown within

figure 1 is a lesion 104, for example a mole, in which the distribution of chromophores is to be examined.

To obtain an image, the skin 103 is contacted directly against the aperture 102. Loose skin and material on the skin surface such as, for example, skin oils, creams etc, leaves a residue on the glass aperture 102 and which, if not removed, will affect the quality of subsequent images.

A nose cone according to the present invention is illustrated in *Figures 2a and 2b*. *Figure 2a* illustrates a schematic representation of a disposable nose cone 7 with a nose cone ending 101 incorporating a glass aperture 102.

The nose cone 7 illustrated in *Figure 2a* comprises a male connection member 201 which is receivable within the handset body to form a resistive fit to secure the nose cone in position. *Figure 2b* illustrates another disposable nose cone similar to that shown in *Figure 2a* with the exception that the nose cone body 7 is elongated with a nose cone ending 101 and a glass aperture 102 of smaller dimensions to the corresponding nose cone illustrated in *Figure 2a*.

To accommodate the differing dimensioned nose cone, a means is provided to adapt the detective field of the detector to accommodate the appropriate sized glass aperture. This is achieved in the present embodiment by the provision of an electrical contact on the nose cone such that, upon attaching the nose cone 7 to the handset 3, a contact is made with a second electrical contact provided on the handset 3. The contact will be configured such that each different dimensioned nose cone interacts with a specific electrical contact on the hand set. Upon electrical contact between a contact on the nose cone and a contact on the handset, the lens which focuses the light remitted from the skin onto the detector is automatically moved to a predetermined position which adapts the detective field of the detector to

correspond with that of the aperture of the nose cone fitted. Consequently, a variety of nose cones of differing dimensions are provided enabling the selection of different image areas.

Alternatively, the lens may be repositioned by a mechanical means, wherein the nose cone carries a probe which, upon location of the nose cone on the handset, is received by the receptacle which moves a slidably mounted lens to the required position corresponding to the length of the probe. Each different dimensioned nose cone will possess a different length probe which determines the final lens position and hence ensure correct focus of the image field of the detector within the handset onto which it is mounted.

The desired nose cone is provided within a sealed bag from which it is removed and mounted onto the handset. Upon use, the nose cone is contacted directly with the skin surface and the skin imaged as described in our previous applications. Following use, the nose cone 7 is detached from the handset and discarded. For subsequent images, a second clean nose cone is attached to the handset.

An alternative embodiment of the present invention is illustrated in *Figure 3*. Attached to a nose cone 7 is a transparent film 302, which forms a covering over the nose cone ending 101 and the transparent glass aperture 102. The film serves as a physical barrier between the glass aperture 102 and the skin and thus prevents contaminants on the skin adhering to the glass. The film 302 is mounted taught within a plastic clip 303 which comprises an arm 304 which extends adjacent to the external surface of the nose cone body 7. In the preferred embodiment, the nose cone 7 is provided with an annular lip 301 which extends about the circumference of the nose cone. The arm of the plastic clip 304 comprises a recess 305 configured to

receive the annular lip **301** of the nose cone **7**, such that the plastic clip **303** and the transparent film **302** mounted therein is held flush with the nose cone end **101** and the glass aperture **102**.

5 The film **302** is preferably prepared from material which is uniformly transparent to light of visible and infra-red wavelengths. Examples of suitable materials would include polyethylene, polyesters, polypropylene, polystyrene, PBDF and polyvinylchloride. The plastic film may also be coated with an adhesive to improve the adherence of the film to the skin.

10 An example of an alternative film that may be incorporated into the clip illustrated in *Figure 3* is shown schematically in *Figure 4*. Located on a first side of the transparent film **302** is a second layer of an optical reflective index matching oil **401** within a defined area **402** which corresponds to the area of the glass aperture **102** of the nose cone **7**. In the preferred embodiment the optical matching index oil is Heine Mineral Oil although any suitable optical index matching oil would suffice such as olive oil or ultrasound coupling gel. 15 In use the optical matching oil reduce reflections from the skin surface. The oil coats the skin on contact diffusing into cracks and abrasions on the skin surface and reducing optical inhomogeneities due to the skin topology.

Also illustrated in *Figure 4* is a further layer of adhesive **403** of defined area **404** which encircles the optical index matching oil area **402**. This 20 arrangement provides for securing the film **302** to the skin surface of a subject providing an area of optical index matching oil **402** of comparable size to the glass aperture **102** such that, upon illumination, light incident from the skin encounters a layer of optical index matching oil prior to contacting the surface of the skin. 25

Figure 5 shows a cross-section through the film illustrated in *Figure 4* along the lines X-X'. The film **302** has, mounted on a first side, a second layer

of optical index matching oil 401 surrounded by a further layer of adhesive 403. As previously described, the film is contacted with the skin via the first side, upon which the second layers of optical index matching oil and adhesive are mounted, and the second side is contacted with the glass aperture preventing contaminants accessing the glass aperture of the nose cone.

Alternatively, the transparent film could be applied directly to the skin of the patient and the nose cone of the handset located against the exposed side of the film to image the area of skin. The film may be secured to the skin by a layer of adhesive. In addition, a layer of optical index matching oil could be provided as previously described with reference to *Figures 4 and 5*.

The films incorporated in the present invention could also comprise a bar code which can be read by a bar code reader mounted within the handset or by the system intended for measuring the light remitted from the skin itself. Consequently the image can be correlated with a specific patient by the bar code for recording purposes. Such a system, could also be used to prevent re-use of a film and hence, cross contamination with material collected from the skin during a previous image process. Example of alternative datamarkings which can be used instead of bar codes include snowflake markings, alphanumeric codes or various forms of optical characters.

Furthermore, the film can be marked with a medical pen to identify areas of a lesion which may be excised. For example, in the case of a malignant melanoma, the images obtained by the apparatus of *Figures A and B* will indicate the distribution of melanin beneath the surface layers of the skin. Consequently, it may be apparent that a larger area of the lesion requires removal compared to what is evident by a surface examination. A

clinician will be able to mark or transfer a mark of the area to be excised onto the film which is subsequently used as a guide to a surgeon when removing the lesion.

5 The following section will describe examples of embodiments of the invention designed to address the problem of stray light accessing the detector.

10 A schematic representation of an example of apparatus according to the invention in use imaging a skin surface of substantial curvature is illustrated in *Figure 6*. The light pipe 3 comprises a nose cone 7 which further houses a nose cone end 101 with a glass aperture 102 mounted therein. Located adjacent to the glass aperture is a finger, represented by the object 601. The finger 601, by virtue of the size and curvature, does not form a complete contact with the glass aperture and consequently stray light (or ambient light from the surroundings) accesses the detector increasing the background intensity and obscuring the image of light remitted from the skin. 15 This makes the interpretation of the image less accurate and, in situations where the light remitted from the illuminated area of skin is low, the remitted light may be undetectable relative to the intensity of stray light accessing the detector.

20 To prevent images being obtained in a situation where too much stray light is present a safety operational sequence is incorporated into the operation of the apparatus to which the invention relates. The operational sequence is illustrated in *Figure 7*.

25 The light pipe is removed from the apparatus and located on the desired area of skin 701. An image is recorded in the absence of incident illumination 702. The intensity of the image detected will depend on two factors, namely the dark current of the detector (which is known during

normal operation) and the presence or absence of stray light accessing the aperture. Consequently, the intensity of the image at one or more points on the detector is set to a predetermined threshold level of stray light considered acceptable. If the image intensity at one or more points is below the defined threshold **703** the normal imaging process continues **704**. If the image intensity at one or more points is above a predetermined threshold level of illumination **705** the image will be rejected **706** and the operator alerted by an alarm or visual message **707** to signify that there is insufficient contact between the desired skin area and the glass aperture.

An example of an embodiment of the invention configured to prevent stray light accessing the detector is shown in *Figure 8*. The nose cone **7**, with glass aperture **101** defined by nose cone end **102**, is contacted with a finger, represented by oval object **601**. Located in between the nose cone ending and the finger **601** is a transparent film **302**, which prevents contaminants from surface of the finger contacting the glass aperture. The transparent film **302** is fixed to the nose cone by an adhesive coating **802**. A circular deformable foam ring **801** is attached to the film such that stray light from the surrounding is blocked from accessing the glass aperture **102**. Any suitable deformable and optically opaque material would suffice in place of the foam ring **801**, suitable examples of which include pigmented silicone rubber and visco-elastic polymers such as a material known as "silly putty" or Plasticine^{RTM}.

An alternative embodiment of the invention is shown in *Figure 9*. A nose cone **7** is provided with an annular lip **301**. A finger **601** is orientated adjacent to the glass aperture **102** with a transparent film located in between. The transparent film **302** is mounted within a plastic clip **303** which receives the nose cone end **101** and is clipped into place by a groove **301** which

receives the lip **301**, as previously discussed with reference to *Figure 3*.

An opaque curtain **901** extends from the clip to associate with the finger **601** to prevent stray light from the surroundings accessing the glass aperture **102**. The curtain can be made from any visually opaque material, with fabric and polymer films the most preferred materials.

During skin imaging it is preferable to have the skin flat and pressed against the glass aperture of the handset such that an even illumination is provided across the skin surface. Consequently, a degree of force is required when pressing the handset onto the skin surface. An operator familiar with the device will have experience of the amount of pressure required, but an unfamiliar operator may provide too much or too little force. Applying too much force is detrimental in situations where the apparatus to which the invention pertains is used for mapping the topology of the dermal-epidermal junction.

Figure 10 illustrates a schematic representation of a nose cone **7** of the skin illumination apparatus in contact with a skin surface **103**. The skin is shown in cross section illustrating the stratum corneum **1001** dermo-epidermal junction **1002** and the boundary between the dermis and the sub-cutaneous tissue **1003**. In normal skin the dermo-epidermal junction exists as an undulating layer of peaks and troughs which define finger like projections or "papillae". In *Figure 10* this layer is shown schematically as peaks **1004** and troughs **1005**. If the nose cone **7** is pressed against the skin surface **103** with more force than is required the skin surface is compressed between the nose cone **7** and the pressure exerted by the underlying sub-cutaneous tissue **1003**. Hence, the thickness of the skin is reduced and the dermal papillae are squashed as illustrated at **1006**. This may lead to false interpretation of the data, particularly in conditions where a flattening of the

dermal papillae is diagnostic feature of a skin condition such as, for example, basal cell carcinoma.

Figure 11 illustrates a modified nose cone receivable on the handset of the apparatus to which the invention pertains. The nose cone **7** comprises the usual nose cone end **101** which defines a transparent glass aperture **102** through which the skin is illuminated. In addition, mounted within the nose cone end **101** are two load cells **1101** and **1102** which are contacted with the skin. The load cells produces an electrical output corresponding to the pressure. The load cell is calibrated to detect an acceptable range of pressure between the skin surface and the nose cone **7**. If the pressure exceeds a predetermined threshold level, the apparatus is configured to prevent an image been obtained and thus prevent a false representation of the skin surface being imaged.

Figure 12 shows an alternative embodiment of the present invention whereby the nose cone **7** is provided with a load cells **1101** and **1102** situated between the nose cone and handset **3**. Applying pressure to the nose cone **7** in turn transfers pressure to the junction between the nose cone **7** and the handset **3**. Similarly, to the embodiment illustrated in *Figure 11*, the load cells are configured to detect pressures above a predetermined maximum.

A mechanical means by which a maximum threshold pressure is detected is shown in *Figure 13*. The nose cone **7** is provided with a circular skin-contacting member **1301** attached to a support **1302** on the nose cone by a resilient spring **1303**. A transparent film **302** is mounted within the aperture defined by the skin-contacting member **1301**. The nose cone is orientated over an area of skin to be imaged and pressed against the surface **103**. The skin contact member is forced towards the nose cone body **7**,

compressing the resilient spring **1303**. If the pressure exceeds a defined threshold, the skin contact member is forced such that the protuberances **1304** contact the microswitch **1305** mounted on the nose cone **7**. The actuation of the microswitch triggers an alarm or visual message alerting the operator to the over pressuring of the skin area and prevents an image being obtained until the pressure is reduced below the predetermined threshold value.

Figure 14 is a flow chart illustrating an example of an operational sequence employed to prevent over pressurising an area of skin. The nose cone is located over the desired area of skin to be imaged **1401**. The load threshold is monitored by the pressure detection means **1402**. If the pressure is too high **1405**, indicated by a signal from the pressure detection means, then the image is rejected **1404** and the operator alerted by audio alarm or visual signal **1407**. If the pressure is below the defined threshold **1404**, the image is obtained as per the normal operational procedure of the skin measurement apparatus **1407**. Consequently, when the operator is alerted to the over pressuring of the skin, the pressure applied may be reduced to below the threshold upon which an image is obtained as per the standard imaging procedure.

A further modification to the nose cone is illustrated in *Figure 15*. During use of the apparatus to which the invention relates, it is advantageous to provide a "clinical view" which, in other words, is an image of the skin surface. In *Figure 15*, the nose cone **7** of the handset is equipped with a two leg members **1501a** and **1505b** rotatably mounted onto a support **1502**. In *Figure 15*, the legs are in the "up position" and the handset is configured for illuminating the skin surface and detecting the light remitted. A lens **1503**, mounted within a handset **3**, focuses the remitted light onto a detector (not

shown). To obtain a clinical view the legs are rotated into a down position, as illustrated in *Figure 16*. The nose cone end **101** is lifted from the skin surface **103** and the position of the lens adjusted to focus on the skin surface **103**. In a preferred embodiment the detector is provided with an auto-focus system which automatically moves the lens **1503** mounted within the handset to focus on the skin surface **103**. Alternatively, the lens may be moved to predetermined position by a mechanical means associated with the rotatable leg members. For example, when the leg members are in a “up position” the lens resides in a fixed position **1503** during imaging of chromophores within the skin and upon moving the leg members to a “down position” the lens is moved to a second predetermined position **1601** to focus on the skin surface.

Although the nose cone is spaced above the skin surface by the leg members in the embodiment illustrated in *Figures 15* and *16*, any spacing means would suffice, such as, for example, a spacer ring or foam ring of defined dimensions such that the nose cone is spaced an optimal distance from the skin surface.

Claims

1. A skin illumination and remitted light detection apparatus,
comprising

5 a light tube defining a transparent glass aperture contactable with the
skin,

illumination means configured to transmit light to said light tube,

detection means to detect light remitted from the skin,

10 wavelength selection means to select the wavelength of light incident
on said detection means,

illumination intensity selection means to select the intensity of light
incident on the detection means, characterised in that

said apparatus further comprises barrier means configured to prevent
direct contact between said glass aperture and said skin.

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2. A skin illumination and remitted light detection apparatus,
comprising

a light tube defining a transparent glass aperture contactable with the
skin,

20 illumination means configured to transmit light to said light tube,

detection means to detect light remitted from the skin,

wavelength selection means to select the wavelength of light incident
on said detection means,

25 illumination intensity selection means to select the intensity of light
incident on the detection means, characterised in that

said apparatus further comprises an ambient light exclusion means to
prevent ambient light accessing said glass aperture.

3. A skin illumination and remitted light detection apparatus,
comprising

5 a light tube defining a transparent glass aperture contactable with the
skin,

illumination means configured to transmit light to said light tube,

detection means to detect light remitted from the skin,

wavelength selection means to select the wavelength of light incident
on said detection means,

10 illumination intensity selection means to select the intensity of light
incident on the detection means, characterised in that

said apparatus further comprises a pressure detection means
configured detect a threshold level of pressure between said light tube and
the skin.

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4. A skin illumination and remitted light detection apparatus,
comprising

a light tube defining a transparent glass aperture contactable with the
skin,

20 illumination means configured to transmit light to said light tube,

detection means to detect light remitted from the skin,

wavelength selection means to select the wavelength of light incident
on said detection means,

25 illumination intensity selection means to select the intensity of light
incident on the detection means, characterised in that

said apparatus further comprises a means for locating said glass
aperture a defined distance from said skin surface such that a clinical view of

the skin surface is obtained.



INVESTOR IN PEOPLE

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Claims searched: 1

21

Examiner: David Brunt
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Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): G1A (AAMX, AFE)

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Other: Online: EPODOC, JAPIO, WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
Y	GB 2156127 A (RICE) see Fig.2	1
Y	EP 0826335 A1 (ESC) see column 5 lines 13-31	1
Y	WO 99/05961 A1 (SPECTRX) note various references to calibration and wavelength selection	1
Y	WO 98/22023 A1 (UNIV BIRMINGHAM) see p.17 ll.15-19 and p.18 ll.18-23	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.